

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON AT TACOMA

## CLALLAM COUNTY,

**Plaintiff,**

No. 3:18-cv-05361

V.

## COMPLAINT

## JURY DEMAND

PURDUE PHARMA, L.P.; PURDUE  
PHARMA, INC.; THE PURDUE FREDERICK  
COMPANY, INC.; ENDO HEALTH  
SOLUTIONS INC.; ENDO  
PHARMACEUTICALS, INC.; JANSSEN  
PHARMACEUTICALS, INC.; JOHNSON &  
JOHNSON; TEVA PHARMACEUTICALS  
INDUSTRIES, LTD.; TEVA  
PHARMACEUTICALS USA, INC.;  
CEPHALON, INC.; ALLERGAN PLC f/k/a  
ACTAVIS PLC; WATSON  
PHARMACEUTICALS, INC n/k/a ACTAVIS,  
INC.; WATSON LABORATORIES, INC.;  
ACTAVIS LLC; ACTAVIS PHARMA, INC.  
f/k/a WATSON PHARMA, INC;  
MALLINCKRODT PLC; MALLINCKRODT,  
LLC; CARDINAL HEALTH, INC.;  
MCKESSON CORPORATION;  
AMERISOURCEBERGEN DRUG  
CORPORATION; and JOHN AND JANE  
DOES 1 THROUGH 100, INCLUSIVE,

### Defendants.

**COMPLAINT  
(3:18-cv-05361)**

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## I. INTRODUCTION

1. The United States is experiencing the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.

2. Since 2000, more than 300,000 Americans have lost their lives to an opioid overdose, more than five times as many American lives as were lost in the entire Vietnam War. On any given day, 145 people will die from opioid overdoses in the United States. Drug overdoses are now the leading cause of death for Americans under age fifty.

3. The opioid crisis has become a public health emergency of unprecedented levels. Plaintiff Clallam County, in Washington State, with approximately 74,000 residents, has been deeply affected by the crisis. Clallam County has consistently had one of the highest opioid overdose death and hospitalization rates in the state. The opioid abuse prevalent throughout the County has affected Plaintiff in numerous ways, not only through the need for increased emergency medical services, but also through increased drug-related offenses affecting law enforcement, jails, and courts, and through additional resources spent on community and social programs, including for the next generation of Clallam residents, who are growing up in the shadow of the opioid epidemic.

4. While the opioid epidemic has hit Clallam County with particular ferocity, the County has been a true leader in responding to the opioid epidemic, working to confront the epidemic caused by Defendants' reckless promotion and distribution of prescription opioids. In 2012, for example, the County identified opioid-related hospitalizations and deaths as a top health priority in the County. And, Clallam County became one of the first jurisdictions in the United States to mandate all opioid overdoses, not just fatal overdoses, be reported to the County.

5. The County also allocates significant resources to prevention and treatment programs including medication-assisted treatment, a syringe exchange program, and other dependency treatment and referral services.

1       6.     But although Clallam County has committed considerable resources to address the  
 2 opioid crisis, to fully address the crisis will require it to spend resources it does not have. It  
 3 would be unfair to require Clallam County to bear all the costs of addressing an epidemic caused  
 4 by Defendants' intentional conduct. Rather, those responsible for the opioid crisis should pay to  
 5 abate the nuisance and harms they have created in Clallam County.

6       7.     The opioid epidemic is no accident. On the contrary, it is the foreseeable  
 7 consequence of Defendants' reckless promotion and distribution of potent opioids for chronic  
 8 pain while deliberately downplaying the significant risks of addiction and overdose.

9       8.     Defendant Purdue set the stage for the opioid epidemic, through the production  
 10 and promotion of its blockbuster drug, OxyContin. Purdue introduced a drug with a narcotic  
 11 payload many times higher than that of previous prescription painkillers, while executing a  
 12 sophisticated, multi-pronged marketing campaign to change prescribers' perception of the risk of  
 13 opioid addiction and to portray opioids as effective treatment for chronic pain. Purdue pushed its  
 14 message of opioids as a low-risk panacea on doctors and the public through every available  
 15 avenue, including through direct marketing, front groups, key opinion leaders, unbranded  
 16 advertising, and hundreds of sales representatives who visited doctors and clinics on a regular  
 17 basis.

18       9.     As sales of OxyContin and Purdue's profits surged, Defendants Endo, Janssen,  
 19 Cephalon, Actavis, and Mallinckrodt—as explained in further detail below—added additional  
 20 prescription opioids, aggressive sales tactics, and dubious marketing claims of their own to the  
 21 deepening crisis. They paid hundreds of millions of dollars to market and promote the drugs,  
 22 notwithstanding their dangers, and pushed bought-and-paid-for “science” supporting the safety  
 23 and efficacy of opioids that lacked any basis in fact or reality. Obscured from the marketing was  
 24 the fact that prescription opioids are not much different than heroin—indeed on a molecular  
 25 level, they are virtually indistinguishable.

1       10.     The opioid epidemic simply could not have become the crisis it is today without  
 2 an enormous supply of pills. Defendants McKesson, Cardinal Health, and AmerisourceBergen  
 3 raked in huge profits from the distribution of opioids around the United States. These companies  
 4 knew precisely the quantities of potent narcotics they were delivering to communities across the  
 5 country, including Clallam County. Yet not only did they intentionally disregard their monitoring  
 6 and reporting obligations under federal law, they also actively sought to evade restrictions and  
 7 obtain higher quotas to enable the distribution of even larger shipments of opioids.

8       11.     Defendants' efforts were remarkably successful: since the mid-1990s, opioids  
 9 have become the most prescribed class of drugs in America. Between 1991 and 2011, opioid  
 10 prescriptions in the U.S. tripled from 76 million to 219 million per year.<sup>1</sup> In 2016, health care  
 11 providers wrote more than 289 million prescriptions for opioid pain medication, enough for  
 12 every adult in the United States to have more than one bottle of pills.<sup>2</sup> In terms of annual sales,  
 13 the increase has been ten-fold; before the FDA approved OxyContin in 1995, annual opioid sales  
 14 hovered around \$1 billion. By 2015, they increased to almost \$10 billion. By 2020, revenues are  
 15 projected to grow to \$18 billion.<sup>3</sup>

16       12.     But Defendants' profits have come at a steep price. Opioids are now the leading  
 17 cause of accidental death in the U.S., surpassing deaths caused by car accidents. Opioid overdose  
 18 deaths (which include prescription opioids as well as heroin) have risen steadily every year, from  
 19 approximately 8,048 in 1999, to 20,422 in 2009, to 33,091 in 2015. In 2016, that toll climbed to  
 20 42,249.<sup>4</sup>

---

21       <sup>1</sup> Nora D. Volkow, MD, *America's Addiction to Opioids: Heroin and Prescription Drug Abuse*, Appearing before  
 22 the Senate Caucus on International Narcotics Control, NIH Nat'l Inst. on Drug Abuse (May 14, 2014),  
<https://www.drugabuse.gov/about-nida/legislative-activities/testimony-to-congress/2016/americas-addiction-to-opioids-heroin-prescription-drug-abuse>.

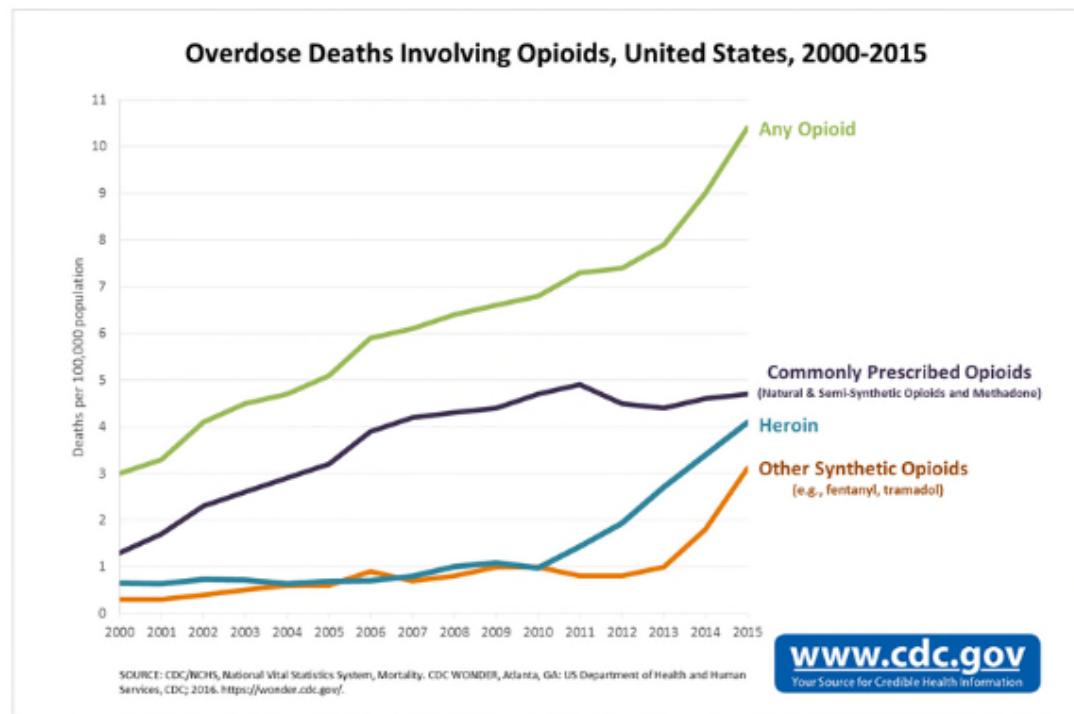
23       <sup>2</sup> *Prevalence of Opioid Misuse*, BupPractice, <https://www.buppractice.com/node/15576> (last updated Mar. 16, 2018).

24       <sup>3</sup> *Report: Opioid pain sales to hit \$18.4B in the U.S. by 2020*, CenterWatch (July 17, 2017),  
<https://www.centerwatch.com/news-online/2017/07/17/report-opioid-pain-sales-hit-18-4b-u-s-2020/#more-31534>.

25       <sup>4</sup> *Overdose Death Rates*, NIH Nat'l Inst. on Drug Abuse, <https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates> (revised Sept. 2017); *Drug Overdose Death Data*, Ctrs. for Disease Control and Prevention, <https://www.cdc.gov/drugoverdose/data/statedeaths.html> (last updated December 19, 2017).

1       13. To put these numbers in perspective: in 1970, when a heroin epidemic swept the  
 2 U.S., there were fewer than 3,000 heroin overdose deaths. And in 1988, around the height of the  
 3 crack epidemic, there were fewer than 5,000 crack overdose deaths recorded. In 2005, at its peak,  
 4 methamphetamine was involved in approximately 4,500 deaths.

5       14. As shown in the graph below, the recent surge in opioid-related deaths involves  
 6 prescription opioids, heroin, and other synthetic opioids. Nearly half of all opioid overdose  
 7 deaths involve a prescription opioid like those manufactured by Defendants,<sup>5</sup> and the increase in  
 8 overdoses from non-prescription opioids is directly attributable to Defendants' success in  
 9 expanding the market for opioids of any kind.



23       15. Just as it has nationally, the opioid epidemic in Clallam County has exacted a  
 24 grim toll. Between 2012 and 2016, at least 54 residents of Clallam County died from opioid-

25  
 26<sup>5</sup> *Understanding the Epidemic*, Ctrs. for Disease Control and Prevention,  
<https://www.cdc.gov/drugoverdose/epidemic/index.html> (last updated Aug. 30, 2017).

1 related overdoses.<sup>6</sup> This rate of approximately 16.5 deaths per 100,000 residents marks a greater  
 2 than 30% increase from the rate the County experienced in the early 2000s.<sup>7</sup> It is also, as noted  
 3 above, one of the highest rates in Washington State.

4       16. Beyond the human cost, the CDC recently estimated that the total economic  
 5 burden of prescription opioid abuse costs the United States \$78.5 billion per year, which includes  
 6 increased costs for health care and addiction treatment, increased strains on human services and  
 7 criminal justice systems, and substantial losses in workforce productivity.<sup>8</sup>

8       17. But even these estimates are conservative. The Council of Economic Advisers—  
 9 the primary advisor to the Executive Office of the President—recently issued a report estimating  
 10 that “in 2015, the economic cost of the opioid crisis was \$504.0 billion, or 2.8% of GDP that  
 11 year. This is over six times larger than the most recently estimated economic cost of the  
 12 epidemic.”<sup>9</sup> Whatever the final tally, there is no doubt that this crisis has had a profound  
 13 economic impact.

14       18. Defendants orchestrated this crisis. Despite knowing about the true hazards of  
 15 their products, Defendants misleadingly advertised their opioids as safe and effective for treating  
 16 chronic pain and pushed hundreds of millions of pills into the marketplace for consumption.  
 17 Through their sophisticated and well-orchestrated campaign, Defendants touted the purported  
 18 benefits of opioids to treat pain and downplayed the risks of addiction. Moreover, even as the  
 19 deadly toll of prescription opioid use became apparent to Defendants in years following  
 20 OxyContin’s launch, Defendants persisted in aggressively selling and distributing prescription  
 21 opioids, while evading their monitoring and reporting obligations, so that massive quantities of

22       <sup>6</sup> *Opioid-related Deaths in Washington State, 2006-2016*, Wash. State Dep’t of Health (May 2017),  
 23 <https://www.doh.wa.gov/Portals/1/Documents/Pubs/346-083-SummaryOpioidOverdoseData.pdf>.

24       <sup>7</sup> *Clallam County Opiate-Related Deaths (Prescription and/or Heroin) 2002-2004 vs. 2011-2013*, U. of Wash.  
 25       Alcohol & Drug Abuse Institute (April 2015) [http://adai.uw.edu/wastate/opiates/clallam\\_opiates\\_2013.pdf](http://adai.uw.edu/wastate/opiates/clallam_opiates_2013.pdf).

26       <sup>8</sup> *CDC Foundation’s New Business Pulse Focuses on Opioid Overdose Epidemic*, Ctrs. for Disease Control and  
 Prevention (Mar. 15, 2017), <https://www.cdc.gov/media/releases/2017/a0315-business-pulse-opioids.html>.

27       <sup>9</sup> *The Underestimated Cost of the Opioid Crisis*, The Council of Econ. Advisers (Nov. 2017),  
 28 <https://static.politico.com/1d/33/4822776641cfbac67f9bc7dbd9c8/the-underestimated-cost-of-the-opioid-crisis-embargoed.pdf>.

addictive opioids continued to pour into Clallam County and other communities around the United States.

19. Defendants consistently, deliberately, and recklessly made and continue to make false and misleading statements regarding, among other things, the low risk of addiction to opioids, opioids' efficacy for chronic pain and ability to improve patients' quality of life with long-term use, the lack of risk associated with higher dosages of opioids, the need to prescribe more opioids to treat withdrawal symptoms, and that risk-mitigation strategies and abuse-deterrent technologies allow doctors to safely prescribe opioids.

20. Because of Defendants' misconduct, Clallam County is experiencing a severe public health crisis and has suffered significant economic damages, including but not limited to increased costs related to public health, opioid-related crimes and emergencies, health care, criminal justice, and public safety. Clallam County has incurred substantial costs in responding to the crisis and will continue to do so in the future.

21. Accordingly, Clallam County brings this action to hold Defendants liable for their misrepresentations regarding the benefits and risks of opioids, as well as for their failure to monitor, detect, investigate, and report suspicious orders of prescription opioids. This conduct (i) violates the Washington Consumer Protection Act, RCW 19.86 *et seq.*, (ii) constitutes a public nuisance under Washington law, (iii) constitutes negligence and gross negligence under Washington law, (iv) has unjustly enriched Defendants, and (v) violates the Racketeer Influenced and Corrupt Organizations Act (“RICO”), 18 U.S.C. §1961, *et seq.*

## II. PARTIES

## Clallam County

22. Plaintiff Clallam County (“Plaintiff” or “Clallam County” or “County”) is a Washington County organized and existing under the laws of the State of Washington, RCW 36.01 *et seq.*

1           **Purdue**

2           23. Defendant Purdue Pharma, L.P. is a limited partnership organized under the laws  
3 of Delaware. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place  
4 of business in Stamford, Connecticut. Defendant The Purdue Frederick Company is a Delaware  
5 corporation with its principal place of business in Stamford, Connecticut. Collectively, these  
6 entities are referred to as “Purdue.”

7           24. Each Purdue entity acted in concert with one another and acted as agents and/or  
8 principals of one another in connection with the conduct described herein.

9           25. Purdue manufactures, promotes, sells, markets, and distributes opioids such as  
10 OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER in the  
11 United States, including in Clallam County.

12          26. Purdue generates substantial sales revenue from its opioids. For example,  
13 OxyContin is Purdue’s best-selling opioid, and since 2009, Purdue has generated between \$2 and  
14 \$3 billion annually in sales of OxyContin alone.

15           **Endo**

16          27. Defendant Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Defendant  
17 Endo Health Solutions Inc. Both are Delaware corporations with their principal place of business  
18 in Malvern, Pennsylvania. Collectively, these entities are referred to as “Endo.”

19          28. Each Endo entity acted in concert with one another and acted as agents and/or  
20 principals of one another in connection with the conduct described herein.

21          29. Endo manufactures, promotes, sells, markets, and distributes opioids such as  
22 Percocet, Opana, and Opana ER in the United States, including in Clallam County.

23          30. Endo generates substantial sales from its opioids. For example, opioids accounted  
24 for more than \$400 million of Endo’s overall revenues of \$3 billion in 2012, and Opana ER  
25 generated more than \$1 billion in revenue for Endo in 2010 and 2013.

1           **Janssen and Johnson & Johnson**

2       31.     Defendant Janssen Pharmaceuticals, Inc. is a Pennsylvania corporation with its  
3 principal place of business in Titusville, New Jersey, and is a wholly owned subsidiary of  
4 Defendant Johnson & Johnson, a New Jersey corporation with its principal place of business in  
5 New Brunswick, New Jersey. Collectively, these entities are referred to as "Janssen."

6       32.     Both entities above acted in concert with one another and acted as agents and/or  
7 principals of one another in connection with the conduct described herein.

8       33.     Johnson & Johnson is the only company that owns more than 10% of Janssen  
9 Pharmaceuticals, Inc., and corresponds with the FDA regarding the drugs manufactured by  
10 Janssen Pharmaceuticals, Inc. Johnson & Johnson also paid prescribers to speak about opioids  
11 manufactured by Janssen Pharmaceuticals, Inc. In short, Johnson & Johnson controls the sale and  
12 development of the drugs manufactured by Janssen Pharmaceuticals, Inc.

13      34.     Janssen manufactures, promotes, sells, markets, and distributes opioids such as  
14 Duragesic, Nucynta, and Nucynta ER in the United States, including in Clallam County. Janssen  
15 stopped manufacturing Nucynta and Nucynta ER in 2015.

16      35.     Janssen generates substantial sales revenue from its opioids. For example,  
17 Duragesic accounted for more than \$1 billion in sales in 2009, and Nucynta and Nucynta ER  
18 accounted for \$172 million in sales in 2014.

19           **Cephalon and Teva**

20      36.     Defendant Cephalon, Inc. ("Cephalon") is a Delaware corporation with its  
21 principal place of business in Frazer, Pennsylvania. Defendant Teva Pharmaceutical Industries,  
22 Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva,  
23 Israel. In 2011, Teva Ltd. acquired Cephalon. Defendant Teva Pharmaceuticals USA, Inc. ("Teva  
24 USA") is a Delaware corporation which is registered to do business in Ohio and is a wholly  
25 owned subsidiary of Teva Ltd. in Pennsylvania. Teva USA acquired Cephalon in October 2011.  
26

1       37. Cephalon manufactures, promotes, sells, and distributes opioids, including Actiq  
 2 and Fentora, in the United States.

3       38. Teva Ltd., Teva USA, and Cephalon work together closely to market and sell  
 4 Cephalon products in the United States. Teva Ltd. conducts all sales and marketing activities for  
 5 Cephalon in the United States through Teva USA and has done so since its October 2011  
 6 acquisition of Cephalon. Teva Ltd. and Teva USA hold out Actiq and Fentora as Teva products  
 7 to the public. Teva USA sells all former Cephalon-branded products through its “specialty  
 8 medicines” division. The FDA-approved prescribing information and medication guide, which  
 9 are distributed with Cephalon opioids, disclose that the guide was submitted by Teva USA, and  
 10 directs physicians to contact Teva USA to report adverse events.

11       39. All of Cephalon’s promotional websites, including those for Actiq and Fentora,  
 12 display Teva Ltd.’s logo.<sup>10</sup> Teva Ltd.’s financial reports list Cephalon’s and Teva USA’s sales as  
 13 its own, and its year-end report for 2012—the year following the Cephalon acquisition in  
 14 October 2011—attributed a 22% increase in its specialty medicine sales to “the inclusion of a  
 15 full year of Cephalon’s specialty sales,” including sales of Fentora.<sup>11</sup> Through interrelated  
 16 operations like these, Teva Ltd. operates in the United States through its subsidiaries Cephalon  
 17 and Teva USA. The United States is the largest of Teva Ltd.’s global markets, representing 53%  
 18 of its global revenue in 2015, and, were it not for the existence of Teva USA and Cephalon, Teva  
 19 Ltd. would conduct those companies’ business in the United States itself.

20       40. Upon information and belief, Teva Ltd. directs the business practices of Cephalon  
 21 and Teva USA, and their profits inure to the benefit of Teva Ltd. as controlling shareholder.  
 22 Collectively, these entities are referred to as “Cephalon.”

23  
 24  
 25       <sup>10</sup> Actiq, <http://www.actiq.com/> (last visited Mar. 19, 2018).

26       <sup>11</sup> *Teva Pharm. Indus. Ltd. Form 20-F*, U.S. Sec. and Exchange Commission (Feb. 12, 2013),  
[http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ\\_TEVA\\_2012.pdf](http://annualreports.com/HostedData/AnnualReportArchive/t/NASDAQ_TEVA_2012.pdf).

1           **Allergan, Actavis, and Watson**

2       41.      Defendant Allergan PLC is a public limited company incorporated in Ireland with  
3 its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March  
4 2015, and the combined company changed its name to Allergan PLC in January 2013.

5       42.      Defendant Actavis, Inc. was acquired by Watson Pharmaceuticals, Inc. in October  
6 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then  
7 Actavis PLC in October 2013.

8       43.      Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal  
9 place of business in Corona, California, and is a wholly owned subsidiary of Allergan PLC (f/k/a  
10 Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.).

11       44.      Defendant Actavis Pharma, Inc. is registered to do business with the Ohio  
12 Secretary of State as a Delaware corporation with its principal place of business in New Jersey  
13 and was formerly known as Watson Pharma, Inc.

14       45.      Defendant Actavis LLC is a Delaware limited liability company with its principal  
15 place of business in Parsippany, New Jersey.

16       46.      Each of these defendants and entities is owned by Defendant Allergan PLC,  
17 which uses them to market and sell its drugs in the United States. Upon information and belief,  
18 Defendant Allergan PLC exercises control over these marketing and sales efforts and profits  
19 from the sale of Allergan/Actavis/Watson products ultimately inure to its benefit. Collectively,  
20 these defendants and entities are referred to as "Actavis."

21       47.      Actavis manufactures, promotes, sells, and distributes opioids, including the  
22 branded drugs Kadian and Norco and generic versions of Kadian, Duragesic, and Opana in the  
23 United States. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc. on  
24 December 30, 2008, and began marketing Kadian in 2009.

1           **Mallinckrodt**

2       48.     Mallinckrodt plc is an Irish public limited company headquartered in Staines-  
 3 upon-Thames, United Kingdom, with its U.S. headquarters in St. Louis, Missouri. Mallinckrodt  
 4 plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of  
 5 Covidien plc, which was fully transferred to Mallinckrodt in June of that year. Mallinckrodt,  
 6 LLC is a limited liability company organized and existing under the laws of the State of  
 7 Delaware and licensed to do business in Washington. Mallinckrodt, LLC is a wholly owned  
 8 subsidiary of Mallinckrodt plc. Mallinckrodt plc and Mallinckrodt, LLC are referred to as  
 9 "Mallinckrodt."

10      49.     Mallinckrodt manufactures, markets, and sells drugs in the United States. As of  
 11 2012, it was the largest U.S. supplier of opioid pain medications. In particular, it is one of the  
 12 largest manufacturers of oxycodone in the U.S.

13      50.     Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is  
 14 extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and  
 15 Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths.

16      51.     While it has sought to develop its branded opioid products, Mallinckrodt has long  
 17 been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received  
 18 approximately 25% of the U.S. Drug Enforcement Administration's ("DEA") entire annual quota  
 19 for controlled substances that it manufactures. Mallinckrodt also estimated, based on IMS Health  
 20 data for the same period, that its generics claimed an approximately 23% market share of DEA  
 21 Schedules II and III opioid and oral solid dose medications.

22      52.     Mallinckrodt operates a vertically integrated business in the United States: (1)  
 23 importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its  
 24 facility in Hobart, New York, and (3) marketing and selling its products to drug distributors,  
 25 specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers  
 26 that have mail-order pharmacies, and hospital buying groups.

1       53. In 2017, Mallinckrodt agreed to settle for \$35 million the Department of Justice's  
2 allegations regarding excessive sales of oxycodone in Florida. The Department of Justice alleged  
3 that even though Mallinckrodt knew that its oxycodone was being diverted to illicit use, it  
4 nonetheless continued to incentivize and supply these suspicious sales, and it failed to notify the  
5 DEA of the suspicious orders in violation of its obligations as a registrant under the Controlled  
6 Substances Act, 21 U.S.C. § 801 *et seq.* ("CSA").

7       54. Defendants Purdue, Endo, Janssen, Cephalon, Actavis, and Mallinckrodt are  
8 collectively referred to as the "Manufacturing Defendants."

9              **AmerisourceBergen**

10       55. Defendant AmerisourceBergen Drug Corporation ("AmerisourceBergen") is a  
11 Delaware corporation with its principal place of business located in Chesterbrook, Pennsylvania.

12       56. According to its 2016 Annual Report, AmerisourceBergen is "one of the largest  
13 global pharmaceutical sourcing and distribution services companies" with "over \$145 billion in  
14 annual revenue."

15       57. AmerisourceBergen is licensed as a "wholesale distributor" to sell prescription  
16 and non-prescription drugs in Washington State, including opioids. It operates a warehouse in  
17 Kent, Washington.

18              **Cardinal Health**

19       58. Defendant Cardinal Health, Inc. ("Cardinal Health") is an Ohio Corporation with  
20 its principal place of business in Dublin, Ohio.

21       59. According to its 2017 Annual Report, Cardinal Health is "a global, integrated  
22 healthcare services and products company serving hospitals, healthcare systems, pharmacies,  
23 ambulatory surgery centers, clinical laboratories and physician offices worldwide . . .  
24 deliver[ing] medical products and pharmaceuticals." In 2017 alone, Cardinal Health generated  
25 revenues of nearly \$130 billion.

1       60. Cardinal Health is licensed as a “wholesale distributor” to sell prescription and  
2 non-prescription drugs in Washington State, including opioids. It operates a warehouse in Fife,  
3 Washington.

4              **McKesson**

5       61. Defendant McKesson Corporation (“McKesson”) is a Delaware Corporation with  
6 its principal place of business in San Francisco, California.

7       62. McKesson is the largest pharmaceutical distributor in North America, delivering  
8 nearly one-third of all pharmaceuticals used in this region.

9       63. According to its 2017 Annual Report, McKesson “partner[s] with pharmaceutical  
10 manufacturers, providers, pharmacies, governments and other organizations in healthcare to help  
11 provide the right medicines, medical products and healthcare services to the right patients at the  
12 right time, safely and cost-effectively.” Additionally, McKesson’s pharmaceutical distribution  
13 business operates and serves thousands of customer locations through a network of twenty-seven  
14 distribution centers, as well as a primary redistribution center, two strategic redistribution centers  
15 and two repackaging facilities, serving all fifty states and Puerto Rico.

16       64. For the fiscal year ending March 31, 2017, McKesson generated revenues of  
17 \$198.5 billion.

18       65. McKesson is licensed as a “wholesale distributor” to sell prescription and non-  
19 prescription drugs in Washington State, including opioids. It operates warehouses in Everett and  
20 Auburn, Washington.

21       66. Collectively, McKesson, AmerisourceBergen, and Cardinal Health (together  
22 “Distributor Defendants”) account for approximately 85% of all drug shipments in the United  
23 States.

24              **John and Jane Does 1-100, inclusive**

25       67. In addition to the Defendants identified herein, the true names, roles, and/or  
26 capacities in the wrongdoing alleged herein of Defendants named John and Jane Does 1 through

1 100, inclusive, are currently unknown to Plaintiff, and thus, are named as Defendants under  
 2 fictitious names as permitted by the rules of this Court. Plaintiff will amend this complaint and  
 3 identify their true identities and their involvement in the wrongdoing at issue, as well as the  
 4 specific causes of action asserted against them when they become known.

### 5 III. JURISDICTION AND VENUE

6 68. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332. The  
 7 Court also has federal question subject matter jurisdiction arising out of Plaintiff's RICO claims  
 8 pursuant to 28 U.S.C. § 1331 and 18 U.S.C. § 1961, *et seq.*

9 69. Venue in this Court is proper under 28 U.S.C. § 1391(b).

### 10 IV. FACTUAL ALLEGATIONS

#### 11 A. Making an Old Drug New Again

##### 12 1. A history and background of opioids in medicine

13 70. The term "opioid" refers to a class of drugs that bind with opioid receptors in the  
 14 brain and includes natural, synthetic, and semi-synthetic opioids.<sup>12</sup> Generally used to treat pain,  
 15 opioids produce multiple effects on the human body, the most significant of which are analgesia,  
 16 euphoria, and respiratory depression. In addition, opioids cause sedation and constipation.

17 71. Most of these effects are medically useful in certain situations, but respiratory  
 18 depression is the primary limiting factor for the use of opioids. While the body develops  
 19 tolerance to the analgesic and euphoric effects of opioids relatively quickly, this is not true with  
 20 respect to respiratory depression. At high doses, opioids can and often do arrest respiration  
 21 altogether. This is why the risk of opioid overdose is so high, and why many of those who  
 22 overdose simply go to sleep and never wake up.

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23  
 24  
 25 <sup>12</sup> At one time, the term "opiate" was used for natural opioids, while "opioid" referred to synthetic substances  
 26 manufactured to mimic opiates. Now, however, most medical professionals use "opioid" to refer broadly to  
 natural, semi-synthetic, and synthetic opioids. A fourth class of opioids, endogenous opioids (e.g., endorphins), is  
 produced naturally by the human body.

1       72. Natural opioids are derived from the opium poppy and have been used since  
 2 antiquity, going as far back as 3400 B.C. The opium poppy contains various opium alkaloids,  
 3 three of which are used commercially today: morphine, codeine, and thebaine.

4       73. A 16th-century European alchemist, Paracelsus, is generally credited with  
 5 developing a tincture of opium and alcohol called laudanum, but it was a British physician a  
 6 century later who popularized the use of laudanum in Western medicine. “Sydenham’s  
 7 laudanum” was a simpler tincture than Paracelsus’s and was widely adopted as a treatment not  
 8 only for pain, but for coughs, dysentery, and numerous other ailments. Laudanum contains  
 9 almost all of the opioid alkaloids and is still available by prescription today.

10      74. Chemists first isolated the morphine and codeine alkaloids in the early 1800s, and  
 11 the pharmaceutical company Merck began large-scale production and commercial marketing of  
 12 morphine in 1827. During the American Civil War, field medics commonly used morphine,  
 13 laudanum, and opium pills to treat the wounded, and many veterans were left with morphine  
 14 addictions. It was upper and middle class white women, however, who comprised the majority of  
 15 opioid addicts in the late 19th-century United States, using opioid preparations widely available  
 16 in pain elixirs, cough suppressants, and patent medicines. By 1900, an estimated 300,000 people  
 17 were addicted to opioids in the United States,<sup>13</sup> and many doctors prescribed opioids solely to  
 18 prevent their patients from suffering withdrawal symptoms.

19      75. Trying to develop a drug that could deliver opioids’ potent pain relief without  
 20 their addictive properties, chemists continued to isolate and refine opioid alkaloids. Heroin, first  
 21 synthesized from morphine in 1874, was marketed commercially by the Bayer Pharmaceutical  
 22 Company beginning in 1898 as a safe alternative to morphine. Heroin’s market position as a safe  
 23 alternative was short-lived, however; Bayer stopped mass-producing heroin in 1913 because of  
 24 its dangers. German chemists then looked to the alkaloid thebaine, synthesizing oxymorphone

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25      26<sup>13</sup> Nick Miroff, *From Teddy Roosevelt to Trump: How drug companies triggered an opioid crisis a century ago*,  
 Washington Post (Oct. 17, 2017), [https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm\\_term=.7832633fd7ca](https://www.washingtonpost.com/news/retropolis/wp/2017/09/29/the-greatest-drug-fiends-in-the-world-an-american-opioid-crisis-in-1908/?utm_term=.7832633fd7ca).

1 and oxycodone from thebaine in 1914 and 1916, respectively, with the hope that the different  
 2 alkaloid source might provide the benefits of morphine and heroin without the drawbacks.

3       76.     But each opioid was just as addictive as the one before it, and eventually the issue  
 4 of opioid addiction could not be ignored. The nation's first Opium Commissioner, Hamilton  
 5 Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our  
 6 prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of  
 7 moral sense and made them beasts who prey upon their fellows . . . it has become one of the  
 8 most fertile causes of unhappiness and sin in the United States."<sup>14</sup>

9       77.     Concerns over opioid addiction led to national legislation and international  
 10 agreements regulating narcotics: the International Opium Convention, signed at the Hague in  
 11 1912, and, in the U.S., the Harrison Narcotics Tax Act of 1914. Opioids were no longer marketed  
 12 as cure-alls and instead were relegated to the treatment of acute pain.

13       78.     Throughout the twentieth century, pharmaceutical companies continued to  
 14 develop prescription opioids, but these opioids were generally produced in combination with  
 15 other drugs, with relatively low opioid content. For example, Percodan, produced by Defendant  
 16 Endo since 1950, is oxycodone and aspirin, and contains just under 5 mg of oxycodone.  
 17 Percocet, manufactured by Endo since 1971, is the combination of oxycodone and  
 18 acetaminophen, with dosage strengths delivering between 2.5 mg and 10 mg of oxycodone.  
 19 Vicodin, a combination of hydrocodone and acetaminophen, was introduced in the U.S. in 1978  
 20 and is sold in strengths of 5 mg, 7.5 mg, and 10 mg of hydrocodone. Defendant Janssen also  
 21 manufactured a drug with 5 mg of oxycodone and 500 mg of acetaminophen, called Tylox, from  
 22 1984 to 2012.

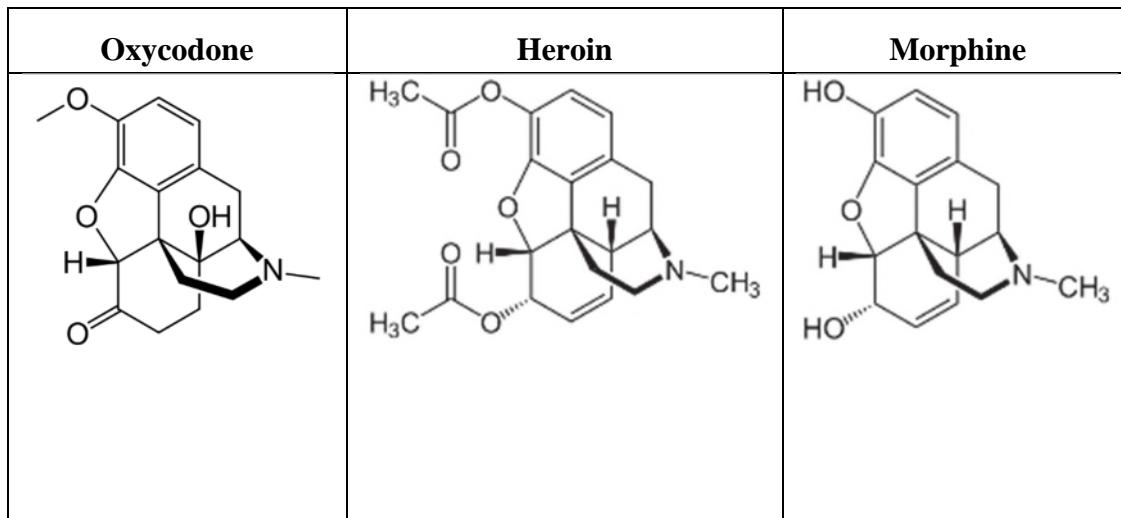
23       79.     In contrast, OxyContin, the product with the dubious honor of the starring role in  
 24 the opioid epidemic, is pure oxycodone. Purdue initially made it available in the following  
 25 dosage strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. In other

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26       <sup>14</sup> *Id.*

1 words, the weakest OxyContin delivers as much narcotic as the strongest Percocet, and some  
 2 OxyContin tablets delivered sixteen times as much as that.

3       80.      Prescription opioids are essentially pharmaceutical heroin; they are synthesized  
 4 from the same plant, have similar molecular structures, and bind to the same receptors in the  
 5 human brain. It is no wonder then that there is a straight line between prescription opioid abuse  
 6 and heroin addiction. Indeed, studies show that over 80% of new heroin addicts between 2008  
 7 and 2010 started with prescription opioids.<sup>15</sup>



17       81.      Medical professionals describe the strength of various opioids in terms of  
 18 “morphine milligram equivalents” (“MME”). According to the CDC, dosages at or above 50  
 19 MME/day double the risk of overdose compared to 20 MME/day, and one study found that  
 20 patients who died of opioid overdose were prescribed an average of 98 MME/day.

21       82.      Different opioids provide varying levels of MMEs. For example, just 33 mg of  
 22 oxycodone provides 50 MME. Thus, at OxyContin’s twice-daily dosing, the 50 MME/day  
 23  
 24

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25       26<sup>15</sup> Jones CM, *Heroin use and heroin use risk behaviors among nonmedical users of prescription opioid pain*  
*relievers - United States, 2002-2004 and 2008-2010*, 132(1-2) Drug Alcohol Depend. 95-100 (Sept. 1, 2013),  
<https://www.ncbi.nlm.nih.gov/pubmed/23410617>.

1 threshold is reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin,  
 2 which Purdue took off the market in 2001, delivered 240 MME.<sup>16</sup>

3       83.     As journalist Barry Meier wrote in his 2003 book *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death*, “In terms of narcotic firepower, OxyContin was a nuclear  
 4 weapon.”<sup>17</sup>

5       84.     Fentanyl, an even more potent and more recent arrival in the opioid tale, is a  
 6 synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First  
 7 developed in 1959 by Dr. Paul Janssen under a patent held by Janssen Pharmaceutica, fentanyl is  
 8 increasingly prevalent in the market for opioids created by Defendants’ promotion, with  
 9 particularly lethal consequences. In many instances, illicit fentanyl is manufactured to look like  
 10 oxycodone tablets, in the light blue color and with the “M” stamp of Defendant Mallinckrodt’s  
 11 30mg oxycodone pills. These lookalike pills have been found around the country, including in  
 12 Washington State.<sup>18</sup>

13       **2.     The Sackler family pioneered the integration of advertising and medicine.**

14       85.     Given the history of opioid use in the U.S. and the medical profession’s resulting  
 15 wariness, the commercial success of Defendants’ prescription opioids would not have been  
 16 possible without a fundamental shift in prescribers’ perception of the risks and benefits of long-  
 17 term opioid use.

18       86.     As it turned out, Purdue was uniquely positioned to execute just such a maneuver,  
 19 thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of  
 20

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21  
 22       <sup>16</sup> The wide variation in the MME strength of prescription opioids renders misleading any effort to capture “market  
 23 share” by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular,  
 24 focuses its business on branded, highly potent pills, causing it to be responsible for a significant percent of the total  
 25 amount of MME in circulation even though it currently claims to have a small percent of the market share in terms  
 26 of pills or prescriptions.

<sup>17</sup> Barry Meier, *Pain Killer: A “Wonder” Drug’s Trail of Addiction and Death* (Rodale 2003).

<sup>18</sup> See e.g., Sharon Bogen, *Illicit fentanyl found locally in fake opioid pills*, Public Health Insider (Oct. 2, 2017), <https://publichealthinsider.com/2017/10/02/illicit-fentanyl-found-locally-in-fake-opioid-pills/>; *Mislabeled painkillers “a fatal overdose waiting to happen,”* CBS News (Feb. 29, 2016, 10:46am), <https://www.cbsnews.com/news/mislabeled-painkillers-a-fatal-overdose-waiting-to-happen/>.

1 Purdue and one of the wealthiest families in America, surpassing the wealth of storied families  
 2 like the Rockefellers, the Mellons, and the Busches.<sup>19</sup> Because of Purdue and, in particular,  
 3 OxyContin, the Sacklers' net worth was \$13 billion as of 2016. Today, all nine members of the  
 4 Purdue board are family members, and all of the company's profits go to Sackler family trusts  
 5 and entities.<sup>20</sup> Yet the Sacklers have avoided publicly associating themselves with Purdue, letting  
 6 others serve as the spokespeople for the company.

7       87.     The Sackler brothers—Arthur, Mortimer, and Raymond—purchased a small  
 8 patent-medicine company called The Purdue Frederick Company in 1952. While all three  
 9 brothers were accomplished psychiatrists, it was Arthur, the oldest, who directed the Sackler  
 10 story, treating his brothers more as his protégés than colleagues, putting them both through  
 11 medical school and essentially dictating their paths. It was Arthur who created the Sackler  
 12 family's wealth, and it was Arthur who created the pharmaceutical advertising industry as we  
 13 know it—laying the groundwork for the OxyContin promotion that would make the Sacklers  
 14 billionaires.

15       88.     Arthur Sackler was both a psychiatrist and a marketing executive, and, by many  
 16 accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at  
 17 Creedmoor State Hospital in New York and the president of an advertising agency called  
 18 William Douglas McAdams. Arthur pioneered both print advertising in medical journals and  
 19 promotion through physician “education” in the form of seminars and continuing medical  
 20 education courses. He understood intuitively the persuasive power of recommendations from  
 21 fellow physicians, and did not hesitate to manipulate information when necessary. For example,  
 22 one promotional brochure produced by his firm for Pfizer showed business cards of physicians  
 23

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24       <sup>19</sup> Alex Morrell, *The OxyContin Clan: The \$14 Billion Newcomer to Forbes 2015 List of Richest U.S. Families*,  
 25     Forbes (July 1, 2015, 10:17am), <https://www.forbes.com/sites/alexmorrell/2015/07/01/the-oxycontin-clan-the-14-billion-newcomer-to-forbes-2015-list-of-richest-u-s-families/#382ab3275e02>.

26       <sup>20</sup> David Armstrong, *The man at the center of the secret OxyContin files*, Stat News (May 12, 2016),  
<https://www.statnews.com/2016/05/12/man-center-secret-oxycontin-files/>.

1 from various cities as if they were testimonials for the drug, but when a journalist tried to contact  
 2 these doctors, he discovered that they did not exist.<sup>21</sup>

3       89. It was Arthur who, in the 1960s, made Valium into the first \$100-million drug, so  
 4 popular it became known as “Mother’s Little Helper.” His expertise as a psychiatrist was key to  
 5 his success; as his biography in the Medical Advertising Hall of Fame notes, it “enabled him to  
 6 position different indications for Roche’s Librium and Valium—to distinguish for the physician  
 7 the complexities of anxiety and psychic tension.”<sup>22</sup> When Arthur’s client, Roche, developed  
 8 Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for  
 9 treatment of anxiety. So Arthur invented a condition he called “psychic tension”—essentially  
 10 stress—and pitched Valium as the solution.<sup>23</sup> The campaign, for which Arthur was compensated  
 11 based on volume of pills sold,<sup>24</sup> was a remarkable success.

12       90. Arthur’s entrepreneurial drive led him to create not only the advertising for his  
 13 clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper  
 14 called the *Medical Tribune*, which he distributed for free to doctors nationwide. Arthur also  
 15 conceived a company now called IMS Health Holdings Inc., which monitors prescribing  
 16 practices of every doctor in the U.S. and sells this valuable data to pharmaceutical companies  
 17 like Defendants, who utilize it to tailor their sales pitches to individual physicians.

18       91. Even as he expanded his business dealings, Arthur was adept at hiding his  
 19 involvement in them. When, during a 1962 Senate hearing about deceptive pharmaceutical  
 20 advertising, he was asked about a public relations company called Medical and Science  
 21 Communications Associates, which distributed marketing from drug companies disguised as  
 22 news articles, Arthur was able to truthfully testify that he never was an officer for nor had any

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23  
 24<sup>21</sup> Meier, *supra* note 17, at 204.

25<sup>22</sup> MAHF Inductees, Arthur M. Sackler, Med. Advert. Hall of Fame, <https://www.mahf.com/mahf-inductees/> (last visited Mar. 22, 2018).

26<sup>23</sup> Meier, *supra* note 17, at 202; *One Family Reaped Billions From Opioids*, WBUR On Point (Oct. 23, 2017), <http://www.wbur.org/onpoint/2017/10/23/one-family-reaped-billions-from-opioids>.

<sup>24</sup> WBUR On Point interview, *supra* note 23.

1 stock in that company. But the company's sole shareholder was his then-wife. Around the same  
 2 time, Arthur also successfully evaded an investigative journalist's attempt to link the Sacklers to  
 3 a company called MD Publications, which had funneled payments from drug companies to an  
 4 FDA official named Henry Welch, who was forced to resign when the scandal broke.<sup>25</sup> Arthur  
 5 had set up such an opaque and layered business structure that his connection to MD Publications  
 6 was only revealed decades later when his heirs were fighting over his estate.

7       92.     Arthur Sackler did not hesitate to manipulate information to his advantage. His  
 8 legacy is a corporate culture that prioritizes profits over people. In fact, in 2007, federal  
 9 prosecutors conducting a criminal investigation of Purdue's fraudulent advertising of OxyContin  
 10 found a "corporate culture that allowed this product to be misbranded with the intent to defraud  
 11 and mislead."<sup>26</sup> Court documents from the prosecution state that "certain Purdue supervisors and  
 12 employees, with the intent to defraud or mislead, marketed and promoted OxyContin as less  
 13 addictive, less subject to abuse and diversion, and less likely to cause tolerance and withdrawal  
 14 than other pain medications . . ."<sup>27</sup> Half a century after Arthur Sackler wedged advertising and  
 15 medicine, Purdue employees were following his playbook, putting product sales over patient  
 16 safety.

### 17       3.     **Purdue and the development of OxyContin**

18       93.     After the Sackler brothers acquired The Purdue Frederick Company in 1952,  
 19 Purdue sold products ranging from earwax remover to antiseptic, and it became a profitable  
 20 business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in  
 21 running Purdue because that would have been a conflict of interest. Raymond Sackler became  
 22 Purdue's head executive while Mortimer Sackler ran Purdue's UK affiliate.

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23  
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 25       <sup>25</sup> Meier, *supra* note 17, at 210-14.

26       <sup>26</sup> Naomi Spencer, *OxyContin manufacturer reaches \$600 million plea deal over false marketing practices*, World  
 27       Socialist Web Site (May 19, 2007), <http://www.wsws.org/en/articles/2007/05/oxy-m19.html>.

<sup>27</sup> Agreed Statement of Facts, *United States. v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

1       94. In the 1980s, Purdue, through its UK affiliate, acquired a Scottish drug producer  
 2 that had developed a sustained-release technology suitable for morphine. Purdue marketed this  
 3 extended-release morphine as MS Contin. It quickly became Purdue's best seller. As the patent  
 4 expiration for MS Contin loomed, Purdue searched for a drug to replace it. Around that time,  
 5 Raymond Sackler's oldest son, Richard Sackler, who was also a trained physician, became more  
 6 involved in the management of the company. Richard Sackler had grand ambitions for the  
 7 company; according to a long-time Purdue sales representative, "Richard really wanted Purdue  
 8 to be big—I mean *really* big."<sup>28</sup> Richard Sackler believed Purdue should develop another use for  
 9 its "Contin" timed-release system.

10      95. In 1990, Purdue's VP of clinical research, Robert Kaiko, sent a memo to Richard  
 11 Sackler and other executives recommending that the company work on a pill containing  
 12 oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because  
 13 it was most commonly prescribed as Percocet, the relatively weak oxycodone-acetaminophen  
 14 combination pill. MS Contin was not only approaching patent expiration but had always been  
 15 limited by the stigma associated with morphine. Oxycodone did not have that problem, and  
 16 what's more, it was sometimes mistakenly called "*oxycodine*," which also contributed to the  
 17 perception of relatively lower potency, because codeine is weaker than morphine. Purdue  
 18 acknowledged using this to its advantage when it eventually pled guilty to criminal charges of  
 19 "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many  
 20 physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to  
 21 make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps . . .  
 22 . that would affect the unique position that OxyContin'" held among physicians.<sup>29</sup>

23      96. For Purdue and OxyContin to be "*really* big," Purdue needed to both distance its  
 24 new product from the traditional view of narcotic addiction risk, and broaden the drug's uses

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25      28 Christopher Glazek, *The Secretive Family Making Billions from the Opioid Crisis*, Esquire (Oct. 16, 2017),  
 26 <http://www.esquire.com/news-politics/a12775932/sackler-family-oxycontin/>.

29 *United States. v. Purdue Frederick Co.*, *supra* note 27.

1 beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in  
 2 March 1995 recommended that if Purdue could show that the risk of abuse was lower with  
 3 OxyContin than with traditional immediate-release narcotics, sales would increase.<sup>30</sup> As  
 4 discussed below, Purdue did not find or generate any such evidence, but this did not stop Purdue  
 5 from making that claim regardless.

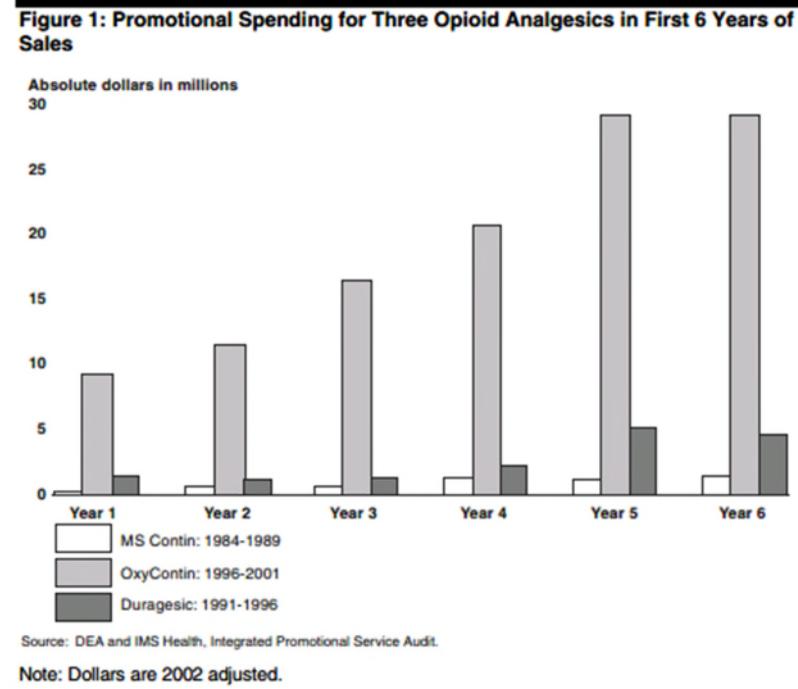
6       97. Despite the fact that there has been little or no change in the amount of pain  
 7 reported in the U.S. over the last twenty years, Purdue recognized an enormous untapped market  
 8 for its new drug. As Dr. David Haddox, a Senior Medical Director at Purdue, declared on the  
 9 Early Show, a CBS morning talk program, "There are 50 million patients in this country who  
 10 have chronic pain that's not being managed appropriately every single day. OxyContin is one of  
 11 the choices that doctors have available to them to treat that."<sup>31</sup>

12       98. In pursuit of these 50 million potential customers, Purdue poured resources into  
 13 OxyContin's sales force and advertising. The graph below shows how promotional spending in  
 14 the first six years following OxyContin's launch dwarfed Purdue's spending on MS Contin or  
 15 Defendant Janssen's spending on Duragesic:<sup>32</sup>

25       <sup>30</sup> Meier, *supra* note 17, at 269.

26       <sup>31</sup> *Id.* at 156.

<sup>32</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, U.S. Gen. Acct. Off. Rep. to Cong. Requesters at 22 (Dec. 2003), <http://www.gao.gov/new.items/d04110.pdf>.



99. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners. Today, one in every five patients who present themselves to physicians' offices with non-cancer pain symptoms or pain-related diagnoses (including acute and chronic pain) receives an opioid prescription.<sup>33</sup>

100. Purdue has generated estimated sales of more than \$35 billion from opioids since 1996, while raking in more than \$3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy.

<sup>33</sup> Deborah Dowell, M.D., Tamara M. Haegerich, Ph.D., and Roger Chou, M.D., *CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016*, Ctrs. for Disease Control and Prevention (Mar. 18, 2016), <https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm> [hereinafter 2016 CDC Guideline].

1 The company's annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its  
 2 2006 sales of \$800 million.

3       101. One might imagine that Richard Sackler's ambitions have been realized. But in  
 4 the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits.  
 5 Under the name of Mundipharma, the Sacklers are looking to new markets for their opioids—  
 6 employing the exact same playbook in South America, China, and India as they did in the United  
 7 States.

8       102. In May 2017, a dozen members of Congress sent a letter to the World Health  
 9 Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world  
 10 through Mundipharma:

11       We write to warn the international community of the deceptive and dangerous  
 12 practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The  
 13 greed and recklessness of one company and its partners helped spark a public health  
 14 crisis in the United States that will take generations to fully repair. We urge the  
 15 World Health Organization (WHO) to do everything in its power to avoid allowing  
 16 the same people to begin a worldwide opioid epidemic. Please learn from our  
 17 experience and do not allow Mundipharma to carry on Purdue's deadly legacy on  
 18 a global stage. . . .

19       Internal documents revealed in court proceedings now tell us that since the early  
 20 development of OxyContin, Purdue was aware of the high risk of addiction it  
 21 carried. Combined with the misleading and aggressive marketing of the drug by its  
 22 partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated  
 23 American communities since the end of the 1990s. Today, Mundipharma is using  
 24 many of the same deceptive and reckless practices to sell OxyContin abroad. . . .

25       In response to the growing scrutiny and diminished U.S. sales, the Sacklers have  
 26 simply moved on. On December 18, the Los Angeles Times published an extremely  
 27 troubling report detailing how in spite of the scores of lawsuits against Purdue for  
 28 its role in the U.S. opioid crisis, and tens of thousands of overdose deaths,  
 29 Mundipharma now aggressively markets OxyContin internationally. In fact,  
 30 Mundipharma uses many of the same tactics that caused the opioid epidemic to  
 31 flourish in the U.S., though now in countries with far fewer resources to devote to  
 32 the fallout.<sup>34</sup>

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34 Letter from Cong. of the U.S., to Dr. Margaret Chan, Dir.-Gen., World Health Org. (May 3, 2017),  
[http://katherineclark.house.gov/\\_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf](http://katherineclark.house.gov/_cache/files/a577bd3c-29ec-4bb9-bdba-1ca71c784113/mundipharma-letter-signatures.pdf).

1       103. Purdue's pivot to untapped markets, after extracting substantial profits from  
 2 communities like Clallam County and leaving the County to address the resulting damage,  
 3 underscores that its actions have been knowing, intentional, and motivated by profits throughout  
 4 this entire tragic story.

5       **B. The Booming Business of Addiction**

6       **1. Other Manufacturing Defendants leapt at the opioid opportunity.**

7       104. Purdue created a market in which the prescription of powerful opioids for a range  
 8 of common aches and pains was not only acceptable but encouraged—but it was not alone.  
 9 Defendants Endo, Janssen, Cephalon, and Actavis, each of which already produced and sold  
 10 prescription opioids, positioned themselves to take advantage of the opportunity Purdue created,  
 11 developing both branded and generic opioids to compete with OxyContin while misrepresenting  
 12 the safety and efficacy of their products.

13       105. Endo, which for decades had sold Percocet and Percodan, both containing  
 14 relatively low doses of oxycodone, moved quickly to develop a generic version of extended-  
 15 release oxycodone to compete with OxyContin, receiving tentative FDA approval for its generic  
 16 version in 2002. As Endo stated in its 2003 Form 10-K, it was the first to file an application with  
 17 the FDA for bioequivalent versions of the 10, 20, and 40 mg strengths of OxyContin, which  
 18 potentially entitled it to 180 days of generic marketing exclusivity—“a significant advantage.”<sup>35</sup>  
 19 Purdue responded by suing Endo for patent infringement, litigating its claims through a full trial  
 20 and a Federal Circuit appeal—unsuccessfully. As the trial court found, and the appellate court  
 21 affirmed, Purdue obtained the oxycodone patents it was fighting to enforce through “inequitable  
 22 conduct”—namely, suggesting that its patent applications were supported by clinical data when  
 23 in fact they were based on an employee’s “insight and not scientific proof.”<sup>36</sup> Endo began selling  
 24 its generic extended-release oxycodone in 2005.

25       

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<sup>35</sup> *Endo Pharm. Holdings, Inc. Form 10-K*, U.S. Sec. and Exchange Comm'n, at 4 (Mar. 15, 2004),  
 26       [http://media.corporate-ir.net/media\\_files/irol/12/123046/reports/10K\\_123103.pdf](http://media.corporate-ir.net/media_files/irol/12/123046/reports/10K_123103.pdf).

<sup>36</sup> *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123, 1131 (Fed. Cir. 2006).

1       106. At the same time as Endo was battling Purdue over generic OxyContin—and as  
 2 the U.S. was battling increasingly widespread opioid abuse—Endo was working on getting  
 3 another branded prescription opioid on the market. In 2002, Endo submitted applications to the  
 4 FDA for both immediate-release and extended-release tablets of oxymorphone, branded as  
 5 Opana and Opana ER.

6       107. Like oxycodone, oxymorphone is not a new drug; it was first synthesized in  
 7 Germany in 1914 and sold in the U.S. by Endo beginning in 1959 under the trade name  
 8 Numorphan, in injectable, suppository, and oral tablet forms. But the oral tablets proved highly  
 9 susceptible to abuse. Called “blues” after the light blue color of the 10 mg pills, Numorphan  
 10 provoked, according to some users, a more euphoric high than heroin, and even had its moment  
 11 in the limelight as the focus of the movie Drugstore Cowboy. As the National Institute on Drug  
 12 Abuse observed in its 1974 report, “Drugs and Addict Lifestyle,” Numorphan was extremely  
 13 popular among addicts for its quick and sustained effect.<sup>37</sup> Endo withdrew oral Numorphan from  
 14 the market in 1979, reportedly for “commercial reasons.”<sup>38</sup>

15       108. Two decades later, however, as communities around the U.S. were first sounding  
 16 the alarm about prescription opioids and Purdue executives were being called to testify before  
 17 Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted  
 18 off a product it had previously shelved after widespread abuse, and pushed it into the  
 19 marketplace with a new trade name and a potent extended-release formulation.

20       109. The clinical trials submitted with Endo’s first application for approval of Opana  
 21 were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be  
 22 revived with naloxone, an opioid antagonist used to counter the effects of an overdose. Endo  
 23 then submitted new “enriched enrollment” clinical trials, in which trial subjects who do not  
 24

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25       37 John Fauber and Kristina Fiore, *Abandoned Painkiller Makes a Comeback*, MedPage Today (May 10, 2015),  
 26       <https://www.medpagetoday.com/psychiatry/addictions/51448>.

38 *Id.*

1 respond to the drug are excluded from the trial, and obtained approval. Endo began marketing  
 2 Opana and Opana ER in 2006.

3       110. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017,  
 4 the FDA sought removal of Opana ER. In its press release, the FDA indicated that “the agency is  
 5 seeking removal based on its concern that the benefits of the drug may no longer outweigh its  
 6 risks. This is the first time the agency has taken steps to remove a currently marketed opioid pain  
 7 medication from sale due to the public health consequences of abuse.”<sup>39</sup> On July 6, 2017, Endo  
 8 agreed to withdraw Opana ER from the market.<sup>40</sup>

9       111. Janssen, which already marketed the Duragesic (fentanyl) patch, developed a new  
 10 opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate  
 11 to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of  
 12 chronic pain in 2011.

13       112. Cephalon also manufactures Actiq, a fentanyl lozenge, and Fentora, a fentanyl  
 14 tablet. As noted above, fentanyl is an extremely powerful synthetic opioid. According to the  
 15 DEA, as little as two milligrams is a lethal dosage for most people. Actiq has been approved by  
 16 the FDA only for the “management of breakthrough cancer pain in patients 16 years and older  
 17 with malignancies who are already receiving and who are tolerant to around-the-clock opioid  
 18 therapy for the underlying persistent cancer pain.”<sup>41</sup> Fentora has been approved by the FDA only  
 19 for the “management of breakthrough pain in cancer patients 18 years of age and older who are  
 20 already receiving and who are tolerant to around-the-clock opioid therapy for their underlying  
 21 persistent cancer pain.”<sup>42</sup>

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22  
 23       <sup>39</sup> Press Release, U.S. Food & Drug Administration, *FDA requests removal of Opana ER for risks related to abuse*  
          (June 8, 2017), <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>.

24       <sup>40</sup> *Endo pulls opioid as U.S. seeks to tackle abuse epidemic*, Reuters (July 6, 2017, 9:59am),  
          <https://www.reuters.com/article/us-endo-intl-opana-idUSKBN19R2II>.

25       <sup>41</sup> *Prescribing Information, ACTIQ®*, U.S. Food & Drug Admin.,  
          [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2009/020747s030lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/020747s030lbl.pdf) (last visited Mar. 19, 2018).

26       <sup>42</sup> *Prescribing Information, FENTORA®*, U.S. Food & Drug Admin.,  
          [https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2012/021947s015lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/021947s015lbl.pdf) (last visited Mar. 19, 2018).

1       113. In 2008, Cephalon pled guilty to a criminal violation of the Federal Food, Drug  
 2 and Cosmetic Act for its misleading promotion of Actiq and two other drugs and agreed to pay  
 3 \$425 million.

4       114. Actavis acquired the rights to Kadian, extended-release morphine, in 2008, and  
 5 began marketing Kadian in 2009. Actavis's opioid products also include Norco, a brand-name  
 6 hydrocodone and acetaminophen pill, first approved in 1997. But Actavis, primarily a generic  
 7 drugmaker, pursued opioid profits through generics, selling generic versions of OxyContin,  
 8 Opana, and Duragesic. In 2013, it settled a patent lawsuit with Purdue over its generic version of  
 9 "abuse-deterrant" OxyContin, striking a deal that would allow it to market its abuse-deterrant  
 10 oxycodone formulation beginning in 2014. Actavis anticipated over \$100 million in gross profit  
 11 from generic OxyContin sales in 2014 and 2015.

12       115. Mallinckrodt's generic oxycodone achieved enough market saturation to have its  
 13 own street name, "M's," based on its imprint on the pills. As noted above, Mallinckrodt was the  
 14 subject of a federal investigation based on diversion of its oxycodone in Florida, where 500  
 15 million of its pills were shipped between 2008 and 2012. Federal prosecutors alleged that 43,991  
 16 orders from distributors and retailers were excessive enough be considered suspicious and should  
 17 have been reported to the DEA.

18       116. Mallinckrodt also pursued a share of the branded opioid market. In 2009,  
 19 Mallinckrodt acquired the U.S. rights to Exalgo, a potent extended-release hydromorphone  
 20 tablet, and began marketing it in 2012. Mallinckrodt further expanded its branded opioid  
 21 portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition,  
 22 Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and  
 23 acetaminophen, which the FDA approved in March 2014. In anticipation of Xartemis XR's

1 approval, Mallinckrodt hired approximately 200 sales representatives to promote it, and CEO  
 2 Mark Trudeau said the drug could generate “hundreds of millions in revenue.”<sup>43</sup>

3       117. All told, the Manufacturing Defendants have reaped enormous profits from the  
 4 addiction crisis they spawned. For example, Opana ER alone generated more than \$1 billion in  
 5 revenue for Endo in 2010 and again in 2013. Janssen earned more than \$1 billion in sales of  
 6 Duragesic in 2009, and Nucynta and Nucynta ER accounted for \$172 million in sales in 2014.

7           **2. Distributor Defendants knowingly supplied dangerous quantities of opioids  
 8 while advocating for limited oversight and enforcement.**

9       118. The Distributor Defendants track and keep a variety of information about the  
 10 pharmacies and other entities to which they sell pharmaceuticals. For example, the Distributor  
 11 Defendants use “know your customer” questionnaires that track the number and types of pills  
 12 their customers sell, absolute and relative amounts of controlled substances they sell, whether the  
 13 customer purchases from other distributors, and types of medical providers in the areas, among  
 14 other information.

15       119. These questionnaires and other sources of information available to the Distributor  
 16 Defendants provide ample data to put the Distributor Defendants on notice of suspicious orders,  
 17 pharmacies, and doctors.

18       120. Nevertheless, the Distributor Defendants refused or failed to identify, investigate,  
 19 or report suspicious orders of opioids to the DEA. Even when the Distributor Defendants had  
 20 actual knowledge that they were distributing opioids to drug diversion rings, they refused or  
 21 failed to report these sales to the DEA.

22       121. By not reporting suspicious opioid orders or known diversions of prescription  
 23 opioids, not only were the Defendants able to continue to sell opioids to questionable customers,  
 24  
 25

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26       <sup>43</sup> Samantha Liss, *Mallinckrodt banks on new painkillers for sales*, St. Louis Bus. Journal (Dec. 30, 2013),  
<http://argentcapital.com/mallinckrodt-banks-on-new-painkillers-for-sales/>.

1 Defendants ensured that the DEA had no basis for decreasing or refusing to increase production  
 2 quotas for prescription opioids.

3       122. The Distributor Defendants collaborated with each other and with the  
 4 Manufacturing Defendants to maintain distribution of excessive amounts of opioids. One  
 5 example of this collaboration came to light through Defendants' work in support of legislation  
 6 called the Ensuring Patient Access and Effective Drug Enforcement (EPAEDE) Act, which was  
 7 signed into law in 2016 and limited the DEA's ability to stop the flow of opioids. Prior to this  
 8 law, the DEA could use an "immediate suspension order" to halt suspicious shipments of pills  
 9 that posed an "imminent" threat to the public. The EPAEDE Act changed the required showing  
 10 to an "immediate" threat—an impossible standard given the fact that the drugs may sit on a shelf  
 11 for a few days after shipment. The law effectively neutralized the DEA's ability to bring  
 12 enforcement actions against distributors.

13       123. The legislation was drafted by a former DEA lawyer, D. Linden Barber, who is  
 14 now a senior vice president at Defendant Cardinal Health. Prior to leaving the DEA, Barber had  
 15 worked with Joseph Rannazzisi, then the chief of the DEA's Office of Diversion Control, to plan  
 16 the DEA's fight against the diversion of prescription drugs. So when Barber began working for  
 17 Cardinal Health, he knew just how to neutralize the effectiveness of the DEA's enforcement  
 18 actions. Barber and other promoters of the EPAEDE Act portrayed the legislation as maintaining  
 19 patient access to medication critical for pain relief. In a 2014 hearing on the bill, Barber testified  
 20 about the "unintended consequences in the supply chain" of the DEA's enforcement actions. But  
 21 by that time, communities across the United States, including Plaintiff Clallam County, were  
 22 grappling with the "unintended consequences" of Defendants' reckless promotion and  
 23 distribution of narcotics.

24       124. Despite egregious examples of drug diversion from around the country, the  
 25 promoters of the EPAEDE Act were successful in characterizing the bill as supporting patients'  
 26 rights. One of the groups supporting this legislation was the Alliance for Patient Access, a "front

1 group” as discussed further below, which purports to advocate for patients’ rights to have access  
 2 to medicines, and whose 2017 list of “associate members and financial supporters” included  
 3 Defendants Purdue, Endo, Johnson & Johnson, Actavis, Mallinckrodt, and Cephalon. In a 2013  
 4 “white paper” titled “Prescription Pain Medication: Preserving Patient Access While Curbing  
 5 Abuse,” the Alliance for Patient Access asserted multiple “unintended consequences” of  
 6 regulating pain medication, including a decline in prescriptions as physicians feel burdened by  
 7 regulations and stigmatized.<sup>44</sup>

8       125. The Distributor Defendants are also part of the activities of the Alliance for  
 9 Patient Access, although their involvement is hidden. One example of their involvement was  
 10 revealed by the metadata of an electronic document: the letter from the Alliance for Patient  
 11 Access in support of the EPAEDE Act. That document was created by Kristen Freitas, a  
 12 registered lobbyist and the vice president for federal government affairs of the Healthcare  
 13 Distributors Alliance (HDA)—the trade group that represents Defendants McKesson, Cardinal  
 14 Health, and AmerisourceBergen.

15       126. Upon information and belief, the collaboration on the EPAEDE Act is just one  
 16 example of how the Manufacturing Defendants and the Distributor Defendants, through third-  
 17 party “front groups” like the Alliance for Patient Access and trade organizations like HDA,  
 18 worked together behind the scenes to ensure that the flow of dangerous narcotics into  
 19 communities across the country would not be restricted, and Defendants collaborated in other  
 20 ways that remain hidden from public view.

21       127. The Distributor Defendants have been the subject of numerous enforcement  
 22 actions by the DEA. In 2008, for example, McKesson was fined \$13.3 million and agreed to  
 23 strengthen its controls by implementing a three-tiered system that would flag buyers who  
 24 exceeded monthly thresholds for opioids. As the opioid crisis deepened, the DEA’s Office of

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25       26 <sup>44</sup> *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, Inst. for Patient Access (Oct.  
 2013), [http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT\\_White-Paper\\_Final.pdf](http://1yh21u3cjptv3xjder1dco9mx5s.wpengine.netdna-cdn.com/wp-content/uploads/2013/12/PT_White-Paper_Final.pdf).

1 Diversion Control, led by Rannazzisi, stepped up enforcement, filing fifty-two immediate  
 2 suspension orders against suppliers and pill mills in 2010 alone. Defendant Cardinal Health was  
 3 fined \$34 million by the DEA in 2013 for failing to report suspicious orders.

4       128. The Distributor Defendants were not simply passive transporters of opioids. They  
 5 intentionally failed to report suspicious orders and actively pushed back against efforts to enforce  
 6 the law and restrict the flow of opioids into communities like Clallam County.

7           **3. Pill mills and overprescribing doctors also placed their financial interests  
 8 ahead of their patients' interests.**

9       129. Prescription opioid manufacturers and distributors were not the only ones to  
 10 recognize an economic opportunity. Around the country, including in Clallam County, certain  
 11 doctors or pain clinics ended up doing brisk business dispensing opioid prescriptions. As Dr.  
 12 Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing, observed, this  
 13 business model meant doctors would “have a practice of patients who’ll never miss an  
 14 appointment and who pay in cash.”<sup>45</sup>

15       130. Moreover, the Manufacturing Defendants’ sales incentives rewarded sales  
 16 representatives who happened to have pill mills within their territories, enticing those  
 17 representatives to look the other way even when their in-person visits to such clinics should have  
 18 raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive  
 19 quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get  
 20 prescriptions. Eventually, the DEA’s diversion unit raided the clinic, and prosecutors filed  
 21 criminal charges against the doctors. But Purdue’s sales representative for that territory, Eric  
 22 Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local  
 23 physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time,  
 24 Wilson was Purdue’s top-ranked sales representative.<sup>46</sup> In response to news stories about this  
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26       <sup>45</sup> Sam Quinones, *Dreamland: The True Tale of America’s Opiate Epidemic* 314 (Bloomsbury Press 2015).

<sup>46</sup> Meier, *supra* note 17, at 298-300.

1 clinic, Purdue issued a statement, declaring that “if a doctor is intent on prescribing our  
 2 medication inappropriately, such activity would continue regardless of whether we contacted the  
 3 doctor or not.”<sup>47</sup>

4       131. Another pill mill, this one in Los Angeles, supplied OxyContin to a drug dealer in  
 5 Everett, Washington. Purdue was alerted to the existence of this pill mill by one of its regional  
 6 sales managers, who in 2009 reported to her supervisors that when she visited the clinic with her  
 7 sales representative, “it was packed with a line out the door, with people who looked like gang  
 8 members,” and that she felt “very certain that this an organized drug ring[.]” She wrote, “This is  
 9 clearly diversion. Shouldn’t the DEA be contacted about this?” But her supervisor at Purdue  
 10 responded that while they were “considering all angles,” it was “really up to [the wholesaler] to  
 11 make the report.” This clinic was the source of 1.1 million pills trafficked to Everett, which is a  
 12 city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to  
 13 inform the authorities.<sup>48</sup> Similarly, Purdue received repeated reports in 2008 from a sales  
 14 representative who visited a family practice doctor in Bothell, Washington; the sales  
 15 representative informed Purdue that many of this doctor’s patients were men in their twenties  
 16 who did not appear to be in pain, who sported diamond studs and \$350 sneakers, and who always  
 17 paid for their 80 mg OxyContin prescriptions in cash. Despite being repeatedly alerted to the  
 18 doctor’s conduct, Purdue did not take any action to report it until three years later.

19       132. Whenever examples of opioid diversion and abuse have drawn media attention,  
 20 the Manufacturing Defendants have consistently blamed “bad actors.” For example, in 2001,  
 21 during a Congressional hearing, Purdue’s attorney Howard Udell answered pointed questions  
 22 about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but  
 23

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24       <sup>47</sup> *Id.*

25       <sup>48</sup> Harriet Ryan, Scott Glover, and Lisa Girion, *How black-market OxyContin spurred a town's descent into crime, addiction and heartbreak*, Los Angeles Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-everett/>; Harriet Ryan, Lisa Girion, and Scott Glover, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times (July 10, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part2/>.

1 not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard  
 2 Paolino. Udell asserted that Purdue was “fooled” by the “bad actor” doctor: “The picture that is  
 3 painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon  
 4 this community, who caused untold suffering. And he fooled us all. He fooled law enforcement.  
 5 He fooled the DEA. He fooled local law enforcement. He fooled us.”<sup>49</sup>

6       133. But given the closeness with which all Defendants monitored prescribing patterns,  
 7 including through IMS Health data, it is highly improbable that they were “fooled.” In fact, a  
 8 local pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and  
 9 alerted authorities. Purdue had the prescribing data from the clinic and alerted no one. Rather, it  
 10 appears Purdue and other Defendants used the IMS Health data to target pill mills and sell more  
 11 pills. Indeed, a Purdue executive referred to Purdue’s tracking system and database as a “gold  
 12 mine” and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

13       134. Sales representatives making in-person visits to such clinics were likewise not  
 14 fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives  
 15 alike, Defendants and their employees turned a collective blind eye, allowing certain clinics to  
 16 dispense staggering quantities of potent opioids and feigning surprise when the most egregious  
 17 examples eventually made the nightly news.

18           **4. Widespread prescription opioid use broadened the market for heroin and**  
 19           **fentanyl.**

20       135. Defendants’ scheme achieved a dramatic expansion of the U.S. market for  
 21 opioids, prescription and non-prescription alike. Heroin and fentanyl use has surged—a  
 22 foreseeable consequence of Defendants’ successful promotion of opioid use coupled with the  
 23 sheer potency of their products.

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 25  
 26       <sup>49</sup> Meier, *supra* note 17, at 179.

1       136. In his book *Dreamland: The True Tale of America's Opiate Epidemic*, journalist  
 2 Sam Quinones summarized the easy entrance of black tar heroin in a market primed by  
 3 prescription opioids:

4       His black tar, once it came to an area where OxyContin had already tenderized the  
 5 terrain, sold not to tapped-out junkies but to younger kids, many from the suburbs,  
 6 most of whom had money and all of whom were white. Their transition from Oxy  
 7 to heroin, he saw, was a natural and easy one. Oxy addicts began by sucking on and  
 8 dissolving the pills' timed-release coating. They were left with 40 or 80 mg of pure  
 9 oxycodone. At first, addicts crushed the pills and snorted the powder. As their  
 10 tolerance built, they used more. To get a bigger bang from the pill, they liquefied it  
 11 and injected it. But their tolerance never stopped climbing. OxyContin sold on the  
 12 street for a dollar a milligram and addicts very quickly were using well over 100  
 13 mg a day. As they reached their financial limits, many switched to heroin, since  
 14 they were already shooting up Oxy and had lost any fear of the needle.<sup>50</sup>

15       137. In a study examining the relationship between the abuse of prescription opioids  
 16 and heroin, researchers found that 75% of those who began their opioid abuse in the 2000s  
 17 reported that their first opioid was a prescription drug.<sup>51</sup> As the graph below illustrates,  
 18 prescription opioids replaced heroin as the first opioid of abuse beginning in the 1990s.

20  
 21  
 22  
 23  
 24  
 25       <sup>50</sup> Quinones, *supra* note 45, at 165-66.

26       <sup>51</sup> Theodore J. Cicero, PhD, Matthew S. Ellis, MPE, Hilary L. Surratt, PhD, *The Changing Face of Heroin Use in*  
*the United States: A Retrospective Analysis of the Past 50 Years*, 71(7) JAMA Psychiatry 821-826 (2014),  
<https://jamanetwork.com/journals/jamapsychiatry/fullarticle/1874575>.



From: The Changing Face of Heroin Use in the United States: A Retrospective Analysis of the Past 50 Years

JAMA Psychiatry. 2014;71(7):821-826. doi:10.1001/jamapsychiatry.2014.366

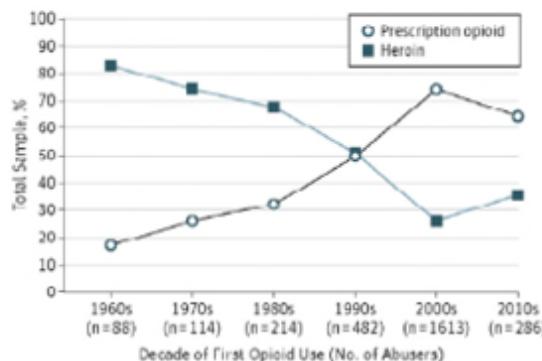


Figure Legend:

Percentage of the Total Heroin-Dependent Sample That Used Heroin or a Prescription Opioid as Their First Opioid of AbuseData are plotted as a function of the decade in which respondents initiated their opioid abuse.

138. The researchers also found that nearly half of the respondents who indicated that  
139. their primary drug was heroin actually preferred prescription opioids, because the prescription  
140. drugs were legal, and perceived as “safer and cleaner.” But, heroin’s lower price point is a  
141. distinct advantage. While an 80 mg OxyContin might cost \$80 on the street, the same high can  
142. be had from \$20 worth of heroin.

143. As noted above, there is little difference between the chemical structures of heroin  
144. and prescription opioids. Between 2005 and 2009, Mexican heroin production increased by over  
145. 600%. And between 2010 and 2014, the amount of heroin seized at the U.S.-Mexico border more  
146. than doubled.

1       140. From 2002 to 2016, fatal overdoses related to heroin in the U.S. increased by  
 2 **533%**—from 2,089 deaths in 2002 to 13,219 deaths in 2016.<sup>52</sup>

3       141. Along with heroin use, fentanyl use is on the rise, as a result of America's  
 4 expanded appetite for opioids. But fentanyl, as noted above, is fifty times more potent than  
 5 heroin, and overdosing is all too easy. Fentanyl is expected to cause over 20,000 overdoses in  
 6 2017.<sup>53</sup>

7       142. As Dr. Caleb Banta-Green, senior research scientist at the University of  
 8 Washington's Alcohol and Drug Abuse Institute, told The Seattle Times in August 2017, "The  
 9 bottom line is opioid addiction is the overall driver of deaths. People will use whatever opioid  
 10 they can get. It's just that which one they're buying is changing a bit."<sup>54</sup>

11      **C. The Manufacturing Defendants Promoted Prescription Opioids Through Several  
 12 Channels.**

13       143. Despite knowing the devastating consequences of widespread opioid use, the  
 14 Manufacturing Defendants engaged in a sophisticated and multi-pronged promotional campaign  
 15 designed to achieve just that. By implementing the strategies pioneered by Arthur Sackler, these  
 16 Defendants were able to achieve the fundamental shift in the perception of opioids that was key  
 17 to making them blockbuster drugs.

18       144. The Manufacturing Defendants disseminated their deceptive statements about  
 19 opioids through several channels.<sup>55</sup> First, these Defendants aggressively and persistently pushed  
 20 opioids through sales representatives. Second, these Defendants funded third-party organizations  
 21 that appeared to be neutral but which served as additional marketing departments for drug  
 22 companies. Third, these Defendants utilized prominent physicians as paid spokespeople—"Key

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23      <sup>52</sup> Niall McCarthy, *U.S. Heroin Deaths Have Increased 533% Since 2002*, Forbes (Sept. 11, 2017, 8:26am),  
 24 <https://www.forbes.com/sites/niallmccarthy/2017/09/11/u-s-heroin-deaths-have-increased-533-since-2002-infographic/#13ab9a531abc>.

25      <sup>53</sup> *Id.*

26      <sup>54</sup> *Opioids: The Leading Cause of Drug Deaths in Seattle Area*, U. of Wash. Sch. of Pub. Health (Aug. 25, 2017),  
[http://sph.washington.edu/news/article.asp?content\\_ID=8595](http://sph.washington.edu/news/article.asp?content_ID=8595).

27      <sup>55</sup> The specific misrepresentations and omissions are discussed below in Section D.

1      Opinion Leaders”—to take advantage of doctors’ respect for and reliance on the  
 2      recommendations of their peers. Finally, these Defendants also used print and online advertising,  
 3      including unbranded advertising, which is not reviewed by the FDA.

4            145. The Manufacturing Defendants spent substantial sums and resources in making  
 5      these communications. For example, Purdue spent more than \$200 million marketing OxyContin  
 6      in 2001 alone.<sup>56</sup>

7            1. **The Manufacturing Defendants aggressively deployed sales representatives  
 8      to push their products.**

9            146. The Manufacturing Defendants communicated to prescribers directly in the form  
 10     of in-person visits and communications from sales representatives.

11           147. The Manufacturing Defendants’ tactics through their sales representatives—also  
 12     known as “detailers”—were particularly aggressive. In 2014, Manufacturing Defendants  
 13     collectively spent well over \$100 million on detailing branded opioids to doctors.

14           148. Each sales representative has a specific sales territory and is responsible for  
 15     developing a list of about 105 to 140 physicians to call on who already prescribe opioids or who  
 16     are candidates for prescribing opioids.

17           149. When Purdue launched OxyContin in 1996, its 300-plus sales force had a total  
 18     physician call list of approximately 33,400 to 44,500. By 2000, nearly 700 representatives had a  
 19     total call list of approximately 70,500 to 94,000 physicians. Each sales representative was  
 20     expected to make about thirty-five physician visits per week and typically called on each  
 21     physician every three to four weeks, while each hospital sales representative was expected to  
 22     make about fifty physician visits per week and call on each facility every four weeks.<sup>57</sup>

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25           <sup>56</sup> *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*,  
 26           107th Cong. 2 (Feb. 12, 2002) (testimony of Paul Goldenheim, Vice President for Research, Purdue Pharma),  
<https://www.gpo.gov/fdsys/pkg/CHRG-107shrg77770/html/CHRG-107shrg77770.htm>.

27           <sup>57</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 32, at 20.

1       150. One of Purdue’s early training memos compared doctor visits to “firing at a  
 2 target,” declaring that “[a]s you prepare to fire your ‘message,’ you need to know where to aim  
 3 and what you want to hit!”<sup>58</sup> According to the memo, the target is physician resistance based on  
 4 concern about addiction: “The physician wants pain relief for these patients without addicting  
 5 them to an opioid.”<sup>59</sup>

6       151. Former sales representative Steven May, who worked for Purdue from 1999 to  
 7 2005, explained to a journalist that the most common objection he heard about prescribing  
 8 OxyContin was that “it’s just too addictive.”<sup>60</sup> In order to overcome that objection and hit their  
 9 “target,” May and other sales representatives were taught to say, “The delivery system is  
 10 believed to reduce the abuse liability of the drug.”<sup>61</sup> May repeated that line to doctors even  
 11 though he “found out pretty fast that it wasn’t true.”<sup>62</sup> He and his coworkers learned quickly that  
 12 people were figuring out how to remove the time-releasing coating, but they continued making  
 13 this misrepresentation until Purdue was forced to remove it from the drug’s label.

14       152. Purdue trained its sales representatives to misrepresent the addiction risk in other  
 15 ways. May explained that he and his coworkers were trained to “refocus” doctors on “legitimate”  
 16 pain patients, and to represent that “legitimate” patients would not become addicted. In addition,  
 17 they were trained to say that the 12-hour dosing made the extended-release opioids less ‘habit-  
 18 forming’ than painkillers that need to be taken every four hours. Similarly, former Purdue sales  
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 20  
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22       <sup>58</sup> Meier, *supra* note 17, at 102.

23       <sup>59</sup> *Id.*

24       <sup>60</sup> David Remnick, *How OxyContin Was Sold to the Masses* (Steven May interview with Patrick Radden Keefe),  
 New Yorker (Oct. 27, 2017), <https://www.newyorker.com/podcast/the-new-yorker-radio-hour/how-oxycontin-was-sold-to-the-masses>.

25       <sup>61</sup> Patrick Radden Keefe, *The Family That Built an Empire of Pain*, New Yorker (Oct. 30, 2017),  
<https://www.newyorker.com/magazine/2017/10/30/the-family-that-built-an-empire-of-pain>; see also Meier, *supra* note 17, at 102 (“Delayed absorption, as provided by OxyContin tablets, is believed to reduce the abuse liability of the drug.”).

26       <sup>62</sup> Keefe, *supra* note 61.

1 manager William Gergely told a Florida state investigator in 2002 that sales representatives were  
 2 instructed to say that OxyContin was “virtually non-addicting” and “non-habit-forming.”<sup>63</sup>

3       153. As Shelby Sherman, a Purdue sales representative from 1974 to 1998, told a  
 4 reporter regarding OxyContin promotion, “It was sell, sell, sell. We were directed to lie. Why  
 5 mince words about it?”<sup>64</sup>

6       154. The Manufacturing Defendants utilized lucrative bonus systems to encourage  
 7 their sales representatives to stick to the script and increase opioid sales in their territories.  
 8 Purdue paid \$40 million in sales incentive bonuses to its sales representatives in 2001 alone, with  
 9 annual bonuses ranging from \$15,000 to nearly \$240,000.<sup>65</sup> The training memo described above,  
 10 in keeping with a Wizard of Oz theme, reminded sales representatives: “A pot of gold awaits you  
 11 ‘Over the Rainbow’!”<sup>66</sup>

12       155. As noted above, these Defendants have also spent substantial sums to purchase,  
 13 manipulate, and analyze prescription data available from IMS Health, which allows them to track  
 14 initial prescribing and refill practices by individual doctors, and in turn to customize their  
 15 communications with each doctor. The Manufacturing Defendants’ use of this marketing data  
 16 was a cornerstone of their marketing plan,<sup>67</sup> and continues to this day.

17       156. The Manufacturing Defendants also aggressively pursued family doctors and  
 18 primary care physicians perceived to be susceptible to their marketing campaigns. The  
 19 Manufacturing Defendants knew that these doctors relied on information provided by  
 20 pharmaceutical companies when prescribing opioids, and that, as general practice doctors seeing

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 23       63 Fred Schulte and Nancy McVicar, *Oxycontin Was Touted As Virtually Nonaddictive, Newly Released State*  
 24       *Records Show*, Sun Sentinel (Mar. 6, 2003), [http://articles.sun-sentinel.com/2003-03-06/news/0303051301\\_1\\_purdue-pharma-oxycontin-william-gergely](http://articles.sun-sentinel.com/2003-03-06/news/0303051301_1_purdue-pharma-oxycontin-william-gergely).

25       64 Glazek, *supra* note 28.

26       65 Art Van Zee, M.D., *The Promotion and Marketing of OxyContin: Commercial Triumph, Public Health Tragedy*,  
 99(2) Am J Public Health 221-27 (Feb. 2009), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2622774/>.

66 Meier, *supra* note 17, at 103.

67 Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 65.

1 a high volume of patients on a daily basis, they would be less likely to scrutinize the companies'  
 2 claims.

3       157. Furthermore, the Manufacturing Defendants knew or should have known the  
 4 doctors they targeted were often poorly equipped to treat or manage pain comprehensively, as  
 5 they often had limited resources or time to address behavioral or cognitive aspects of pain  
 6 treatment or to conduct the necessary research themselves to determine whether opioids were as  
 7 beneficial as these Defendants claimed. In fact, the majority of doctors and dentists who  
 8 prescribe opioids are not pain specialists. For example, a 2014 study conducted by pharmacy  
 9 benefit manager Express Scripts reviewing narcotic prescription data from 2011 to 2012  
 10 concluded that of the more than 500,000 prescribers of opioids during that time period, *only* 385  
 11 were identified as pain specialists.<sup>68</sup>

12       158. When the Manufacturing Defendants presented these doctors with sophisticated  
 13 marketing material and apparently scientific articles that touted opioids' ability to easily and  
 14 safely treat pain, many of these doctors began to view opioids as an efficient and effective way to  
 15 treat their patients.

16       159. In addition, sales representatives aggressively pushed doctors to prescribe  
 17 stronger doses of opioids. For example, one Purdue sales representative in Florida wrote about  
 18 working for a particularly driven regional manager named Chris Sposato and described how  
 19 Sposato would drill the sales team on their upselling tactics:

20       It went something like this. "Doctor, what is the highest dose of OxyContin you  
 21 have ever prescribed?" "20mg Q12h." "Doctor, if the patient tells you their pain  
 22 score is still high you can increase the dose 100% to 40mg Q12h, will you do that?"  
 23 "Okay." "Doctor, what if that patient then came back and said their pain score was  
 24 still high, did you know that you could increase the OxyContin dose to 80mg Q12h,  
 25 would you do that?" "I don't know, maybe." "Doctor, but you do agree that you  
 26 would at least Rx the 40mg dose, right?" "Yes."

The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin. Miami

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<sup>68</sup> *A Nation in Pain*, Express Scripts (Dec. 9, 2014), <http://lab.express-scripts.com/lab/publications/a-nation-in-pain>.

1 District reps have told me that on work sessions with [Sposato] they would sit in  
 2 the car and role play for as long as it took until [Sposato] was convinced the rep  
 3 was delivering the message with perfection.

4 160. The Manufacturing Defendants used not only incentives but competitive pressure  
 5 to push sales representatives into increasingly aggressive promotion. One Purdue sales  
 6 representative recalled the following scene: "I remember sitting at a round table with others from  
 7 my district in a regional meeting while everyone would stand up and state the highest dose that  
 8 they had suckered a doctor to prescribe. The entire region!!"

9 161. Sales representatives also quickly learned that the prescription opioids they were  
 10 promoting were dangerous. For example, May had only been at Purdue for two months when he  
 11 found out that a doctor he was calling on had just lost a family member to an OxyContin  
 12 overdose.<sup>69</sup> And as another sales representative wrote on a public forum:

13 Actions have consequences - so some patient gets Rx'd the 80mg OxyContin when  
 14 they probably could have done okay on the 20mg (but their doctor got "sold" on  
 15 the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and  
 16 takes out a few 80's... next they're at a pill party with other teens and some kid  
 17 picks out a green pill from the bowl... they go to sleep and don't wake up (because  
 18 they don't understand respiratory depression) Stupid decision for a teen to  
 19 make...yes... but do they really deserve to die?

20 162. These sales representatives targeted their efforts at local doctors in Washington  
 21 State, such as, for example, Dr. Frank Li, the former medical director of several pain clinics  
 22 (including one in Everett, Washington, near the Tulalip Reservation) who eventually had his  
 23 medical license suspended for improperly prescribing opioids. Indeed, during detailers' frequent  
 24 visits to Dr. Li, they often noted circumstances that should have led them to discontinue sales  
 25 calls and report Dr. Li and his staff to the appropriate authorities. Instead, they continued to  
 26 target him for detailing visits that incited him to prescribe even more opioids, with disastrous  
 consequences for public health.

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<sup>69</sup> Remnick, *supra* note 60.

1       163. In addition, detailers told providers at Dr. Li's clinic that the Washington State  
 2 opioid prescription guidelines were wrong and overly conservative, including those related to  
 3 calculating the relative strength of different brands of opioids. These detailers often urged  
 4 Dr. Li's staff to give patients more opioids, and particular brands of opioids, even when this was  
 5 incorrect or conflicted with Washington State guidelines or other medical information.

6       164. Purdue's sales call notes also repeatedly reference how busy Dr. Li and his staff  
 7 were—which, combined with the exceptionally high number of opioid prescriptions written by  
 8 Dr. Li, should have been another red flag that OxyContin and other opioids were likely being  
 9 abused.

10      165. The Manufacturing Defendants' sales representatives also provided health care  
 11 providers with pamphlets, visual aids, and other marketing materials designed to increase the rate  
 12 of opioids prescribed to patients. These sales representatives knew the doctors they visited relied  
 13 on the information they provided, and that the doctors had minimal time or resources to  
 14 investigate the materials' veracity independently.

15      166. Sales representatives were also given bonuses when doctors whom they had  
 16 detailed wrote prescriptions for their company's drug. Because of this incentive system, sales  
 17 representatives stood to gain significant bonuses if they had a pill mill in their sales region.<sup>70</sup>  
 18 Sales representatives could be sure that doctors and nurses at pill mills would be particularly  
 19 receptive to their messages and incentives, and receive "credit" for the many prescriptions these  
 20 pill mills wrote.

21      167. The Manufacturing Defendants applied this combination of intense competitive  
 22 pressure and lucrative financial incentives because they knew that sales representatives, with  
 23 their frequent in-person visits with prescribers, were incredibly effective. In fact, manufacturers'  
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25      26<sup>70</sup> Indeed, Defendants often helped their sales representatives find and target such pill mills. As recently as 2016,  
 Purdue commissioned a marketing study to help target Washington prescribers and spread its deceptive message  
 regarding opioids, and on information and belief, utilized its sale representatives to carry out these strategies.

1 internal documents reveal that they considered sales representatives their “most valuable  
 2 resource.”<sup>2</sup>

3       **2. The Manufacturing Defendants bankrolled seemingly independent “front**  
 4 **groups” to promote opioid use and fight restrictions on opioids.**

5       168. The Manufacturing Defendants funded, controlled, and operated third-party  
 6 organizations that communicated to doctors, patients, and the public the benefits of opioids to  
 7 treat chronic pain. These organizations—also known as “front groups”—appeared independent  
 8 and unbiased. But in fact, they were but additional paid mouthpieces for the drug manufacturers.  
 9 These front groups published prescribing guidelines and other materials that promoted opioid  
 10 treatment as a way to address patients’ chronic pain. The front groups targeted doctors, patients,  
 11 and lawmakers, all in coordinated efforts to promote opioid prescriptions.

12       169. The Manufacturing Defendants spent significant financial resources contributing  
 13 to and working with these various front groups to increase the number of opioid prescriptions  
 14 written.

15       170. The most prominent front group utilized by the Manufacturing Defendants was  
 16 the **American Pain Foundation** (APF), which received more than \$10 million from opioid drug  
 17 manufacturers, including Defendants, from 2007 through 2012. For example, Purdue contributed  
 18 \$1.7 million and Endo also contributed substantial sums to the APF.<sup>71</sup>

19       171. Throughout its existence, APF’s operating budget was almost entirely comprised  
 20 of contributions from prescription opioid manufacturers. For instance, nearly 90% of APF’s \$5  
 21 million annual budget in 2010 came from “donations” from some of the Manufacturing  
 22 Defendants, and by 2011, APF was entirely dependent on grants from drug manufacturers,  
 23 including from Purdue and Endo. Not only did Defendants control APF’s purse strings, APF’s  
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26       <sup>71</sup>Charles Ornstein and Tracy Weber, *The Champion of Painkillers*, ProPublica (Dec. 23, 2011, 9:15am),  
<https://www.propublica.org/article/the-champion-of-painkillers>.

1 board of directors was comprised of doctors who were on Defendants' payrolls, either as  
 2 consultants or speakers at medical events.<sup>72</sup>

3       172. Although holding itself out as an independent advocacy group promoting patient  
 4 well-being, APF consistently lobbied against federal and state proposals to limit opioid use.

5       173. Another prominent front group was the **American Academy of Pain Medicine**  
 6 (AAPM), which has received over \$2.2 million in funding since 2009 from opioid drug  
 7 manufacturers, including Defendants. Like APF, AAPM presented itself as an independent and  
 8 non-biased advocacy group representing physicians practicing in the field of pain medicine, but  
 9 in fact was just another mouthpiece the Manufacturing Defendants used to push opioids on  
 10 doctors and patients.<sup>73</sup>

11       174. Both the APF and the AAPM published treatment guidelines and sponsored and  
 12 hosted medical education programs that touted the benefits of opioids to treat chronic pain while  
 13 minimizing and trivializing their risks. The treatment guidelines the front groups published—  
 14 many of which are discussed in detail below—were particularly important to Defendants in  
 15 ensuring widespread acceptance for opioid therapy to treat chronic pain. Defendants realized,  
 16 just as the CDC has, that such treatment guidelines can “change prescribing practices,” because  
 17 they appear to be unbiased sources of evidence-based information, even when they are in reality  
 18 marketing materials.

19       175. For instance, the AAPM, in conjunction with the **American Pain Society** (APS),  
 20 issued comprehensive guidelines in 2009 titled “Guideline for the Use of Chronic Opioid  
 21 Therapy in Chronic Noncancer Pain – Evidence Review” (“2009 Guidelines”). The 2009  
 22 Guidelines promoted opioids as “safe and effective” for treating chronic pain, despite  
 23 acknowledging limited evidence to support this statement. Unsurprisingly, the Manufacturing

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 25       <sup>72</sup> *Id.*

26       <sup>73</sup> Tracy Weber and Charles Ornstein, *Two Leaders in Pain Treatment Have Long Ties to Drug Industry*, ProPublica  
 (Dec. 23, 2011, 9:14am), <https://www.propublica.org/article/two-leaders-in-pain-treatment-have-long-ties-to-drug-industry>.

1 Defendants have widely referenced and promoted these guidelines, issued by front groups these  
 2 Defendants funded and controlled. These 2009 Guidelines are still available online today.<sup>74</sup>

3       176. The **Alliance for Patient Access** (APA), discussed above, was established in  
 4 2006, along with the firm that runs it, Woodberry Associates LLC. The APA describes itself as  
 5 “a national network of physicians dedicated to ensuring patient access to approved therapies and  
 6 appropriate clinical care,” but its list of “Associate Members and Financial Supporters” contains  
 7 thirty drug companies, including each of the Manufacturing Defendants named in this lawsuit. In  
 8 addition, the APA’s board members include doctors who have received hundreds of thousands of  
 9 dollars in payments from drug companies. As discussed above, the APA has been a vocal critic  
 10 of policies restricting the flow of opioids and has supported efforts to curtail the DEA’s ability to  
 11 stop suspicious orders of prescription drugs.

12       177. The “white paper” issued by the APA in 2013 also echoed a favorite narrative of  
 13 the Manufacturing Defendants, the supposed distinction between “legitimate patients” on the one  
 14 hand and “addicts” on the other, asserting that one “unintended consequence” of regulating pain  
 15 medication would be that “[p]atients with legitimate medical needs feel stigmatized, treated like  
 16 addicts.”<sup>75</sup>

17       178. Another group utilized by the Manufacturing Defendants to encourage opioid  
 18 prescribing practices, a University of Wisconsin-based organization known as the **Pain & Policy**  
 19 **Studies Group**, received \$2.5 million from pharmaceutical companies to promote opioid use and  
 20 discourage the passing of regulations against opioid use in medical practice. The Pain & Policy  
 21 Studies Group wields considerable influence over the nation’s medical schools as well as within

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 25       <sup>74</sup> *Clinical Guideline for the Use of Chronic Opioid Therapy in Chronic Noncancer Pain*, Am. Pain Soc’y,  
          <http://americanpainsociety.org/uploads/education/guidelines/chronic-opioid-therapy-cncp.pdf> (last visited Mar. 22,  
          2018).

26       <sup>75</sup> *Prescription Pain Medication: Preserving Patient Access While Curbing Abuse*, *supra* note 44.

1 the medical field in general.<sup>76</sup> Purdue was the largest contributor to the Pain & Policy Studies  
 2 Group, paying approximately \$1.6 million between 1999 and 2010.<sup>77</sup>

3       179. The **Federation of State Medical Boards** (FSMB) of the United States is a  
 4 national non-profit organization that represents the seventy-state medical and osteopathic boards  
 5 of the United States and its territories and co-sponsors the United States Medical Licensing  
 6 Examination. Beginning in 1997, FSMB developed model policy guidelines around the treatment  
 7 of pain, including opioid use. The original initiative was funded by the Robert Wood Johnson  
 8 Foundation, but subsequently AAPM, APS, the University of Wisconsin Pain & Policy Studies  
 9 Group, and the American Society of Law, Medicine, & Ethics all made financial contributions to  
 10 the project.

11       180. FSMB's 2004 *Model Policy* encourages state medical boards "to evaluate their  
 12 state pain policies, rules, and regulations to identify *any regulatory restrictions or barriers that*  
 13 *may impede the effective use of opioids* to relieve pain."<sup>78</sup> (Emphasis added).

14       181. One of the most significant barriers to convincing doctors that opioids were safe  
 15 to prescribe to their patients for long-term treatment of chronic pain was the fact that many of  
 16 those patients would, in fact, become addicted to opioids. If patients began showing up at their  
 17 doctors' offices with obvious signs of addiction, the doctors would, of course, become concerned  
 18 and likely stop prescribing opioids. And, doctors might stop believing the Manufacturing  
 19 Defendants' claims that addiction risk was low.

20       182. To overcome this hurdle, the Manufacturing Defendants promoted a concept  
 21 called "pseudoaddiction." These Defendants told doctors that when their patients appeared to be  
 22 addicted to opioids—for example, asking for more and higher doses of opioids, increasing doses

23       <sup>76</sup> *The Role of Pharmaceutical Companies in the Opioid Epidemic*, Addictions.com,  
 24       <https://www.addictions.com/opiate/the-role-of-pharmaceutical-companies-in-the-opioid-epidemic/> (last visited  
 Mar. 22, 2018).

25       <sup>77</sup> John Fauber, *UW group ends drug firm funds*, Journal Sentinel (Apr. 20, 2011),  
 26       <http://archive.jsonline.com/watchdog/watchdogreports/120331689.html>.

27       <sup>78</sup> *Model Policy for the Use of Controlled Substances for the Treatment of Pain*, Fed'n of St. Med. Boards of the  
 U.S., Inc. (May 2004), <http://www.painpolicy.wisc.edu/sites/www.painpolicy.wisc.edu/files/model04.pdf>.

1 themselves, or claiming to have lost prescriptions in order to get more opioids—this was not  
 2 actual addiction. Rather, the Manufacturing Defendants told doctors what appeared to be classic  
 3 signs of addiction were actually just signs of undertreated pain. The solution to this  
 4 “pseudoaddiction”: more opioids. Instead of warning doctors of the risk of addiction and helping  
 5 patients to wean themselves off of powerful opioids and deal with their actual addiction, the  
 6 Manufacturing Defendants pushed even more dangerous drugs onto patients.

7       183. The FSMB’s *Model Policy* gave a scientific veneer to this fictional and overstated  
 8 concept. The policy defines “pseudoaddiction” as “[t]he iatrogenic syndrome resulting from the  
 9 misinterpretation of relief seeking behaviors as though they are drug-seeking behaviors that are  
 10 commonly seen with addiction” and states that these behaviors “resolve upon institution of  
 11 effective analgesic therapy.”<sup>79</sup>

12       184. In May 2012, Senate Finance Committee Chairman Max Baucus and senior  
 13 Committee member Chuck Grassley initiated an investigation into the connections of the  
 14 Manufacturing Defendants with medical groups and physicians who have advocated increased  
 15 opioid use.<sup>80</sup> In addition to Purdue, Endo, and Janssen, the senators sent letters to APF, APS,  
 16 AAPM, FSMB, the University of Wisconsin Pain & Policy Studies Group, the Joint Commission  
 17 on Accreditation of Healthcare Organization, and the Center for Practical Bioethics, requesting  
 18 from each “a detailed account of all payments/transfers received from corporations and any  
 19 related corporate entities and individuals that develop, manufacture, produce, market, or promote  
 20 the use of opioid-based drugs from 1997 to the present.”<sup>81</sup>

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 23       <sup>79</sup> *Id.*

24       <sup>80</sup> *Baucus, Grassley Seek Answers about Opioid Manufacturers’ Ties to Medical Groups*, U.S. Senate Comm. on  
 25 Fin. (May 8, 2012), <https://www.finance.senate.gov/chairmans-news/baucus-grassley-seek-answers-about-opioid-manufacturers-ties-to-medical-groups>.

26       <sup>81</sup> Letter from U.S. Senate Comm. on Fin. to Am. Pain Found. (May 8, 2012),  
<https://www.finance.senate.gov/imo/media/doc/05092012%20Baucus%20Grassley%20Opioid%20Investigation%20Letter%20to%20American%20Pain%20Foundation2.pdf>.

1       185. On the same day as the senators' investigation began, APF announced that it  
 2 would "cease to exist, effective immediately."<sup>82</sup>

3       **3. "It was pseudoscience": the Manufacturing Defendants paid prominent  
 4 physicians to promote their products.**

5       186. The Manufacturing Defendants retained highly credentialed medical professionals  
 6 to promote the purported benefits and minimal risks of opioids. Known as "Key Opinion  
 7 Leaders" or "KOLs," these medical professionals were often integrally involved with the front  
 8 groups described above. The Manufacturing Defendants paid these KOLs substantial amounts to  
 9 present at Continuing Medical Education ("CME") seminars and conferences, and to serve on  
 10 their advisory boards and on the boards of the various front groups.

11       187. The Manufacturing Defendants also identified doctors to serve as speakers or  
 12 attend all-expense-paid trips to programs with speakers.<sup>83</sup> The Manufacturing Defendants used  
 13 these trips and programs—many of them lavish affairs—to incentivize the use of opioids while  
 14 downplaying their risks, bombarding doctors with messages about the safety and efficacy of  
 15 opioids for treating long-term pain. Although often couched in scientific certainty, the  
 16 Manufacturing Defendants' messages were false and misleading, and helped to ensure that  
 17 millions of Americans would be exposed to the profound risks of these drugs.

18       188. It is well documented that this type of pharmaceutical company symposium  
 19 influences physicians' prescribing, even though physicians who attend such symposia believe  
 20 that such enticements do not alter their prescribing patterns.<sup>84</sup> For example, doctors who were  
 21 invited to these all-expenses-paid weekends in resort locations like Boca Raton, Florida, and  
 22 Scottsdale, Arizona, wrote twice as many prescriptions as those who did not attend.<sup>85</sup>

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<sup>82</sup> Charles Ornstein and Tracy Weber, *American Pain Foundation Shuts Down as Senators Launch Investigation of Prescription Narcotics*, ProPublica (May 8, 2012, 8:57pm), <https://www.propublica.org/article/senate-panel-investigates-drug-company-ties-to-pain-groups>.

24       <sup>83</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 65.

25       <sup>84</sup> *Id.*

26       <sup>85</sup> Harriet Ryan, Lisa Girion and Scott Glover, *OxyContin goes global — "We're only just getting started"*, Los Angeles Times (Dec. 18, 2016), <http://www.latimes.com/projects/la-me-oxycontin-part3/>.

1       189. The KOLs gave the impression they were independent sources of unbiased  
 2 information, while touting the benefits of opioids through their presentations, articles, and books.  
 3 KOLs also served on committees and helped develop guidelines such as the 2009 Guidelines  
 4 described above that strongly encouraged the use of opioids to treat chronic pain.

5       190. One of the most prominent KOLs for the Manufacturing Defendants' opioids was  
 6 Dr. Russell Portenoy. A respected leader in the field of pain treatment, Dr. Portenoy was highly  
 7 influential. Dr. Andrew Kolodny, cofounder of Physicians for Responsible Opioid Prescribing,  
 8 described him "lecturing around the country as a religious-like figure. The megaphone for  
 9 Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling  
 10 message: 'Docs have been letting patients suffer; nobody really gets addicted; it's been  
 11 studied.'"<sup>86</sup>

12       191. As one organizer of CME seminars, who worked with Portenoy and Purdue,  
 13 pointed out, "had Portenoy not had Purdue's money behind him, he would have published some  
 14 papers, made some speeches, and his influence would have been minor. With Purdue's millions  
 15 behind him, his message, which dovetailed with their marketing plans, was hugely magnified."<sup>87</sup>

16       192. In recent years, some of the Manufacturing Defendants' KOLs have conceded that  
 17 many of their past claims in support of opioid use lacked evidence or support in the scientific  
 18 literature.<sup>88</sup> Dr. Portenoy himself specifically admitted that he overstated the drugs' benefits and  
 19 glossed over their risks, and that he "gave innumerable lectures in the late 1980s and '90s about  
 20 addiction that weren't true."<sup>89</sup> He mused, "Did I teach about pain management, specifically about

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<sup>86</sup> Quinones, *supra* note 45, at 314.

24       <sup>87</sup> *Id.* at 136.

25       <sup>88</sup> See, e.g., John Fauber, *Painkiller boom fueled by networking*, Journal Sentinel (Feb. 18, 2012),  
<http://archive.jsonline.com/watchdog/watchdogreports/painkiller-boom-fueled-by-networking-dp3p2rn-139609053.html/> (finding that a key Endo KOL acknowledged that opioid marketing went too far).

26       <sup>89</sup> Thomas Catan and Evan Perez, *A Pain-Drug Champion Has Second Thoughts*, Wall Street Journal (Dec. 17, 2012, 11:36am), <https://www.wsj.com/articles/SB10001424127887324478304578173342657044604>.

1 opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I  
 2 guess I did . . . We didn't know then what we know now.”<sup>90</sup>

3       193. Dr. Portenoy did not need “the standards of 2012” to discern evidence-based  
 4 science from baseless claims, however. When interviewed by journalist Barry Meier for his 2003  
 5 book, *Pain Killer*, Dr. Portenoy was more direct: “It was pseudoscience. I guess I’m going to  
 6 have always to live with that one.”<sup>91</sup>

7       194. Dr. Portenoy was perhaps the most prominent KOL for prescription opioids, but  
 8 he was far from the only one. In fact, Dr. Portenoy and a doctor named Perry Fine co-wrote *A*  
 9 *Clinical Guide to Opioid Analgesia*, which contained statements that conflict with the CDC’s  
 10 *2016 Guideline for Prescribing Opioids for Chronic Pain*, such as the following examples  
 11 regarding respiratory depression and addiction:

12           At clinically appropriate doses, . . . respiratory rate typically does not decline.  
 13 Tolerance to the respiratory effects usually develops quickly, and doses can be  
 steadily increased without risk.

14           Overall, the literature provides evidence that the outcomes of drug abuse and  
 15 addiction are rare among patients who receive opioids for a short period (ie, for  
 acute pain) and among those with no history of abuse who receive long-term  
 16 therapy for medical indications.<sup>92</sup>

17       195. Dr. Fine is a Professor of Anesthesiology at the University of Utah School of  
 18 Medicine’s Pain Research Center. He has served on Purdue’s advisory board, provided medical  
 19 legal consulting for Janssen, and participated in CME activities for Endo, along with serving in  
 20 these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid  
 21 Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that  
 22 group from 2011 to 2013, and was also on the board of directors of APF.<sup>93</sup>

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23           <sup>90</sup> *Id.*

24           <sup>91</sup> Meier, *supra* note 17, at 277.

25           <sup>92</sup> Perry G. Fine, MD and Russell K. Portenoy, MD, *A Clinical Guide to Opioid Analgesia* 20 and 34, McGraw-Hill  
 Companies (2004), <http://www.thblack.com/links/RSD/OpioidHandbook.pdf>.

26           <sup>93</sup> Scott M. Fishman, MD, *Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion*,  
 306 (13) JAMA 1445 (Sept. 20, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104464?redirect=true>.

1       196. In 2011, he and Dr. Scott Fishman, discussed below, published a letter in *JAMA*  
 2 called “Reducing Opioid Abuse and Diversion,” which emphasized the importance of  
 3 maintaining patient access to opioids.<sup>94</sup> The editors of *JAMA* found that both doctors had  
 4 provided incomplete financial disclosures and made them submit corrections listing all of their  
 5 ties to the prescription painkiller industry.<sup>95</sup>

6       197. Dr. Fine also failed to provide full disclosures as required by his employer, the  
 7 University of Utah. For example, Dr. Fine told the university that he had received under \$5,000  
 8 in 2010 from Johnson & Johnson for providing “educational” services, but Johnson & Johnson’s  
 9 website states that the company paid him \$32,017 for consulting, promotional talks, meals and  
 10 travel that year.<sup>96</sup>

11       198. In 2012, along with other KOLs, Dr. Fine was investigated for his ties to drug  
 12 companies as part of the Senate investigation of front groups described above. When Marianne  
 13 Skolek, a reporter for the online news outlet Salem-News.com and a critic of opioid overuse,  
 14 wrote an article about him and another KOL being investigated, Dr. Fine fired back, sending a  
 15 letter to her editor accusing her of poor journalism and saying that she had lost whatever  
 16 credibility she may have had. He criticized her for linking him to Purdue, writing, “I have never  
 17 had anything to do with Oxycontin development, sales, marketing or promotion; I have never  
 18 been a Purdue Pharma speaker”—neglecting to mention, of course, that he served on Purdue’s  
 19 advisory board, as the *JAMA* editors had previously forced him to disclose.<sup>97</sup>

20       199. Another Utah physician, Dr. Lynn Webster, was the director of Lifetree Clinical  
 21 Research & Pain Clinic in Salt Lake City from 1990 to 2010, and in 2013 was the president of  
 22 AAPM (one of the front groups discussed above). Dr. Webster developed a five-question survey

23       <sup>94</sup> Perry G. Fine, MD and Scott M. Fishman, MD, *Reducing Opioid Abuse and Diversion*, 306 (4) *JAMA* 381 (July  
 24 27, 2011), <https://jamanetwork.com/journals/jama/article-abstract/1104144?redirect=true>.

25       <sup>95</sup> *Incomplete Financial Disclosures in: Reducing Opioid Abuse and Diversion*, 306 (13) *JAMA* 1446 (Oct. 5,  
 26 2011), <https://jamanetwork.com/journals/jama/fullarticle/1104453>.

96 Weber and Ornstein, *Two Leaders in Pain Treatment*, *supra* note 73.

97 Marianne Skolek, *Doctor Under Senate Investigation Lashes Out at Journalist*, Salem News (Aug. 12, 2012,  
 8:45pm), <http://www.salem-news.com/articles/august122012/perry-fine-folo-ms.php>.

1 he called the Opioid Risk Tool, which he asserted would “predict accurately which individuals  
 2 may develop aberrant behaviors when prescribed opioids for chronic pain.”<sup>98</sup> He published  
 3 books titled *The Painful Truth: What Chronic Pain Is Really Like and Why It Matters to Each of*  
 4 *Us and Avoiding Opioid Abuse While Managing Pain.*

5 200. Dr. Webster and the Lifetree Clinic were investigated by the DEA for  
 6 overprescribing opioids after twenty patients died from overdoses. In keeping with the opioid  
 7 industry’s promotional messages, Dr. Webster apparently believed the solution to patients’  
 8 tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.  
 9 Tina Webb, a Lifetree patient who overdosed in 2007, was taking as many as thirty-two pain  
 10 pills a day in the year before she died, all while under doctor supervision.<sup>99</sup> Carol Ann Bosley,  
 11 who sought treatment for pain at Lifetree after a serious car accident and multiple spine  
 12 surgeries, quickly became addicted to opioids and was prescribed increasing quantities of pills; at  
 13 the time of her death, she was on seven different medications totaling approximately 600 pills a  
 14 month.<sup>100</sup> Another woman, who sought treatment from Lifetree for chronic low back pain and  
 15 headaches, died at age forty-two after Lifetree clinicians increased her prescriptions to fourteen  
 16 different drugs, including multiple opioids, for a total of 1,158 pills a month.<sup>101</sup>

17 201. By these numbers, Lifetree resembles the pill mills and “bad actors” that the  
 18 Manufacturing Defendants blame for opioid overuse. But Dr. Webster was an integral part of  
 19 Defendants’ marketing campaigns, a respected pain specialist who authored numerous CMEs  
 20 sponsored by Endo and Purdue. And the Manufacturing Defendants promoted his Opioid Risk  
 21  
 22

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23 <sup>98</sup> Lynn Webster and RM Webster, *Predicting aberrant behaviors in opioid-treated patients: preliminary validation*  
 24 *of the Opioid Risk Tool* 6 (6) Pain Med. 432 (Nov.-Dec. 2005), <https://www.ncbi.nlm.nih.gov/pubmed/16336480>.

25 <sup>99</sup> Jesse Hyde and Daphne Chen, *The untold story of how Utah doctors and Big Pharma helped drive the national*  
*opioid epidemic*, Deseret News (Oct. 26, 2017, 12:01am), <https://www.deseretnews.com/article/900002328/the-untold-story-of-how-utah-doctors-and-big-pharma-helped-drive-the-national-opioid-epidemic.html>.

26 <sup>100</sup> Stephanie Smith, *Prominent pain doctor investigated by DEA after patient deaths*, CNN (Dec. 20, 2013,  
 7:06am), <http://www.cnn.com/2013/12/20/health/pain-pillar/index.html>.

<sup>101</sup> *Id.*

1 Tool and similar screening questionnaires as measures that allow powerful opioids to be  
 2 prescribed for chronic pain.

3       202. Even in the face of patients' deaths, Dr. Webster continues to promote a pro-  
 4 opioid agenda, even asserting that alternatives to opioids are risky because "[i]t's not hard to  
 5 overdose on NSAIDs or acetaminophen."<sup>102</sup> He argued on his website in 2015 that DEA  
 6 restrictions on the accessibility of hydrocodone harm patients, and in 2017 tweeted in response to  
 7 CVS Caremark's announcement that it will limit opioid prescriptions that "CVS Caremark's new  
 8 opioid policy is wrong, and it won't stop illegal drugs."<sup>103</sup>

9       203. Another prominent KOL is Dr. Scott M. Fishman, the Chief of the Department of  
 10 Pain Medicine at University of California, Davis. He has served as president of APF and AAPM,  
 11 and as a consultant and a speaker for Purdue, in addition to providing the company grant and  
 12 research support. He also has had financial relationships with Endo and Janssen. He wrote a  
 13 book for the FSMB called *Responsible Opioid Use: A Physician's Guide*, which was distributed  
 14 to over 165,000 physicians in the U.S.

15       204. Dr. Fishman and Dr. Fine, along with Dr. Seddon Savage, published an editorial  
 16 in the Seattle Times in 2010, arguing that Washington legislation proposed to combat  
 17 prescription opioid abuse would harm patients, in particular by requiring chronic pain patients to  
 18 consult with a pain specialist before receiving a prescription for a moderate to high dose of an  
 19 opioid.<sup>104</sup>

20       205. These KOLs and others—respected specialists in pain medicine—proved to be  
 21 highly effective spokespeople for the Manufacturing Defendants.

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22  
 23       <sup>102</sup> APF releases opioid medication safety module, Drug Topics (May 10, 2011),  
 24       <http://drugtopics.modernmedicine.com/drug-topics/news/modernmedicine/modern-medicine-news/apf-releases-opioid-medication-safety-module>.

25       <sup>103</sup> Lynn Webster, MD (@LynnRWebsterMD), Twitter (Dec. 7, 2017, 5:45pm),  
 26       <https://twitter.com/LynnRWebsterMD/status/938887130545360898>.

104 Perry G. Fine, Scott M. Fishman, and Seddon R. Savage, *Bill to combat prescription abuse really will harm*  
 patients in pain, Seattle Times (Mar. 16, 2010, 4:39pm),  
[http://old.seattletimes.com/html/opinion/2011361572\\_guest17fine.html](http://old.seattletimes.com/html/opinion/2011361572_guest17fine.html).

1           **4. The Manufacturing Defendants used “unbranded” advertising as a platform**  
 2           **for their misrepresentations about opioids.**

3           206. The Manufacturing Defendants also aggressively promoted opioids through  
 4           “unbranded advertising” to generally tout the benefits of opioids without specifically naming a  
 5           particular brand-name opioid drug. Instead, unbranded advertising is usually framed as “disease  
 6           awareness”—encouraging consumers to “talk to your doctor” about a certain health condition  
 7           without promoting a specific product. A trick often used by pharmaceutical companies,  
 8           unbranded advertising gives the pharmaceutical companies considerable leeway to make  
 9           sweeping claims about health conditions or classes of drugs. In contrast, a “branded”  
 10          advertisement that identifies a specific medication and its indication (i.e., the condition which the  
 11          drug is approved to treat) must also include possible side effects and contraindications—what the  
 12          FDA Guidance on pharmaceutical advertising refers to as “fair balance.” Branded advertising is  
 13          also subject to FDA review for consistency with the drug’s FDA-approved label.

14          207. Unbranded advertising allows pharmaceutical manufacturers to sidestep those  
 15          requirements; “fair balance” and consistency with a drug’s label are not required.

16          208. By engaging in unbranded advertising, the Manufacturing Defendants were and  
 17          are able to avoid FDA review and issue general statements to the public including that opioids  
 18          improve function, that addiction usually does not occur, and that withdrawal can easily be  
 19          managed. The Manufacturing Defendants’ unbranded advertisements either did not disclose the  
 20          risks of addiction, abuse, misuse, and overdose, or affirmatively denied or minimized those risks.

21          209. Through the various marketing channels described above—all of which the  
 22          Manufacturing Defendants controlled, funded, and facilitated, and for which they are legally  
 23          responsible—these Defendants made false or misleading statements about opioids despite the  
 24          lack of scientific evidence to support their claims, while omitting the true risk of addiction and  
 25          death.

1      **D. Specific Misrepresentations Made by the Manufacturing Defendants.**

2      210. All the Manufacturing Defendants have made and/or continue to make false or  
 3 misleading claims in the following areas: (1) the low risk of addiction to opioids, (2) opioids'  
 4 efficacy for chronic pain and ability to improve patients' quality of life with long-term use, (3)  
 5 the lack of risk associated with higher dosages of opioids, (4) the need to prescribe more opioids  
 6 to treat withdrawal symptoms, and (5) that risk-mitigation strategies and abuse-deterring  
 7 technologies allow doctors to safely prescribe opioids for chronic use. These illustrative but non-  
 8 exhaustive categories of the Manufacturing Defendants' misrepresentations about opioids are  
 9 described in detail below.

10     **1. The Manufacturing Defendants falsely claimed that the risk of opioid abuse  
 11 and addiction was low.**

12     211. Collectively, the Manufacturing Defendants have made a series of false and  
 13 misleading statements about the low risk of addiction to opioids over the past twenty years. The  
 14 Manufacturing Defendants have also failed to take sufficient remedial measures to correct their  
 15 false and misleading statements.

16     212. The Manufacturing Defendants knew that many physicians were hesitant to  
 17 prescribe opioids other than for acute or cancer-related pain because of concerns about addiction.  
 18 Because of this general perception, sales messaging about the low risk of addiction was a  
 19 fundamental prerequisite misrepresentation.

20     213. Purdue launched OxyContin in 1996 with the statement that OxyContin's  
 21 patented continuous-release mechanism "is believed to reduce the abuse liability." This  
 22 statement, which appeared in OxyContin's label and which sales representatives were taught to  
 23 repeat verbatim, was unsupported by any studies, and was patently false. The continuous-release  
 24 mechanism was simple to override, and the drug correspondingly easy to abuse. This fact was  
 25 known, or should have been known, to Purdue prior to its launch of OxyContin, because people  
 26 had been circumventing the same continuous-release mechanism for years with MS Contin,

1 which in fact commanded a high street price because of the dose of pure narcotic it delivered. In  
 2 addition, with respect to OxyContin, Purdue researchers notified company executives, including  
 3 Raymond and Richard Sackler, by email that patients in their clinical trials were abusing the drug  
 4 despite the timed-release mechanism.<sup>105</sup>

5       214. In 2007, as noted above, Purdue pleaded guilty to misbranding a drug, a felony  
 6 under the Food, Drug, and Cosmetic Act. 21 U.S.C. § 331(a)(2). As part of its guilty plea,  
 7 Purdue agreed that certain Purdue supervisors and employees had, “with the intent to defraud or  
 8 mislead, marketed and promoted OxyContin as less addictive, less subject to abuse and  
 9 diversion, and less likely to cause tolerance and withdrawal than other pain medications” in the  
 10 following ways:

11       Trained PURDUE sales representatives and told some health care providers that it  
 12 was more difficult to extract the oxycodone from an OxyContin tablet for the  
 13 purpose of intravenous abuse, although PURDUE’s own study showed that a drug  
 14 abuser could extract approximately 68% of the oxycodone from a single 10mg  
 15 OxyContin tablet by crushing the tablet, stirring it in water, and drawing the  
 16 solution through cotton into a syringe;

17       Told PURDUE sales representatives they could tell health care providers that  
 18 OxyContin potentially creates less chance for addiction than immediate-release  
 19 opioids;

20       Sponsored training that taught PURDUE sales supervisors that OxyContin had  
 21 fewer “peak and trough” blood level effects than immediate-release opioids  
 22 resulting in less euphoria and less potential for abuse than short-acting opioids;

23       Told certain health care providers that patients could stop therapy abruptly without  
 24 experiencing withdrawal symptoms and that patients who took OxyContin would  
 25 not develop tolerance to the drug; and

26       Told certain health care providers that OxyContin did not cause a “buzz” or  
 27 euphoria, caused less euphoria, had less addiction potential, had less abuse  
 28 potential, was less likely to be diverted than immediate-release opioids, and could  
 29 be used to “weed out” addicts and drug seekers.<sup>106</sup>

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<sup>105</sup> WBUR On Point interview, *supra* note 23.

<sup>106</sup> *United States v. Purdue Frederick Co.*, *supra* note 27; see also, Plea Agreement, *United States v. Purdue Frederick Co.*, No. 1:07-cr-00029 (W.D. Va. May 10, 2007).

1       215. All of these statements were false and misleading. But Purdue had not stopped  
 2 there. Purdue—and later the other Defendants—manipulated scientific research and utilized  
 3 respected physicians as paid spokespeople to convey its misrepresentations about low addiction  
 4 risk in much more subtle and pervasive ways, so that the idea that opioids used for chronic pain  
 5 posed a low addiction risk became so widely accepted in the medical community that Defendants  
 6 were able to continue selling prescription opioids for chronic pain—even after Purdue’s criminal  
 7 prosecution.

8       216. When it launched OxyContin, Purdue knew it would need data to overcome  
 9 decades of wariness regarding opioid use. It needed some sort of research to back up its  
 10 messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as  
 11 part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants)  
 12 found this “research” in the form of a one-paragraph letter to the editor published in the *New*  
 13 *England Journal of Medicine* (NEJM) in 1980.

14       217. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of  
 15 addiction “rare” for patients treated with opioids.<sup>107</sup> They had analyzed a database of hospitalized  
 16 patients who were given opioids in a controlled setting to ease suffering from acute pain. These  
 17 patients were not given long-term opioid prescriptions or provided opioids to administer to  
 18 themselves at home, nor was it known how frequently or infrequently and in what doses the  
 19 patients were given their narcotics. Rather, it appears the patients were treated with opioids for  
 20 short periods of time under in-hospital doctor supervision.

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 26       <sup>107</sup> Jane Porter and Herschel Jick, MD, *Addiction Rare in Patients Treated with Narcotics*, 302(2) N Engl J Med. 123 (Jan. 10, 1980), <http://www.nejm.org/doi/pdf/10.1056/NEJM198001103020221>.

1  
 2                   **ADDICTION RARE IN PATIENTS TREATED**  
 3                   **WITH NARCOTICS**

4                   *To the Editor:* Recently, we examined our current files to deter-  
 5                   mine the incidence of narcotic addiction in 39,946 hospitalized  
 6                   medical patients<sup>1</sup> who were monitored consecutively. Although  
 7                   there were 11,882 patients who received at least one narcotic prep-  
 8                   aration, there were only four cases of reasonably well documented  
 9                   addiction in patients who had no history of addiction. The addic-  
 10                  tion was considered major in only one instance. The drugs im-  
 11                  plicated were meperidine in two patients,<sup>2</sup> Percodan in one, and  
 12                  hydromorphone in one. We conclude that despite widespread use of  
 13                  narcotic drugs in hospitals, the development of addiction is rare in  
 14                  medical patients with no history of addiction.

15                   JANE PORTER  
 16                   HERSHEL JICK, M.D.  
 17                   Boston Collaborative Drug  
 18                   Surveillance Program

19                   Waltham, MA 02154                   Boston University Medical Center

- 20                   1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Sloane D.  
 21                   Comprehensive drug surveillance. *JAMA*. 1970; 213:1455-60.  
 22                   2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical  
 23                   patients. *J Clin Pharmacol*. 1978; 18:180-8.

24                  218. As Dr. Jick explained to a journalist years later, he submitted the statistics to  
 25                  NEJM as a letter because the data were not robust enough to be published as a study, and that  
 26                  one could not conclude anything about long-term use of opioids from his figures.<sup>108</sup> Dr. Jick also  
 27                  recalled that no one from drug companies or patient advocacy groups contacted him for more  
 28                  information about the data.<sup>109</sup>

29                  219. Nonetheless, the Manufacturing Defendants regularly invoked this letter as proof  
 30                  of the low addiction risk in connection with taking opioids despite its obvious shortcomings.  
 31                  These Defendants' egregious misrepresentations based on this letter included claims that *less*  
 32                  than one percent of opioid users become addicted.

33                  220. The limited facts of the study did not deter the Manufacturing Defendants from  
 34                  using it as definitive proof of opioids' safety. The enormous impact of the Manufacturing  
 35                  Defendants' misleading amplification of this letter was well documented in another letter

26                  

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<sup>108</sup> Meier, *supra* note 17, at 174.

<sup>109</sup> *Id.*

1 published in NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been  
 2 irresponsibly cited and in some cases “grossly misrepresented.” In particular, the authors of this  
 3 letter explained:

4 [W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily  
 5 and uncritically cited as evidence that addiction was rare with long-term opioid  
 6 therapy. We believe that this citation pattern contributed to the North American  
 7 opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about  
 8 the risk of addiction associated with long-term opioid therapy . . .<sup>110</sup>

9       221. Unfortunately, by the time of this analysis and the CDC’s findings in 2016, the  
 10 damage had already been done. “It’s difficult to overstate the role of this letter,” said Dr. David  
 11 Juurlink of the University of Toronto, who led the analysis. “It was the key bit of literature that  
 12 helped the opiate manufacturers convince front-line doctors that addiction is not a concern.”<sup>111</sup>

13       222. The Manufacturing Defendants successfully manipulated the 1980 Porter and Jick  
 14 letter as the “evidence” supporting their fundamental misrepresentation that the risk of opioid  
 15 addiction was low when opioids were prescribed to treat pain. For example, in its 1996 press  
 16 release announcing the release of OxyContin, Purdue advertised that the “fear of addiction is  
 17 exaggerated” and quoted the chairman of the American Pain Society Quality of Care Committee,  
 18 who claimed that “there is very little risk of addiction from the proper uses of these [opioid]  
 19 drugs for pain relief.”<sup>112</sup>

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 23       <sup>110</sup> Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B. Stanbrook, M.D., Ph.D., Irfan Al  
 24 Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of Opioid Addiction*, 376 N Engl J Med  
 25 2194-95 (June 1, 2017), <http://www.nejm.org/doi/full/10.1056/NEJMc1700150#t=article>.

26       <sup>111</sup> *Painful words: How a 1980 letter fueled the opioid epidemic*, STAT News (May 31, 2017),  
<https://www.statnews.com/2017/05/31/opioid-epidemic-nejm-letter/>.

27       <sup>112</sup> Press Release, OxyContin, *New Hope for Millions of Americans Suffering from Persistent Pain: Long-Acting*  
 28 *OxyContin Tablets Now Available to Relieve Pain* (May 31, 1996, 3:47pm),  
<http://documents.latimes.com/oxycontin-press-release-1996/>.

1

2 PR Newswire

3 **May** 31, 1996, Friday - 15:47 Eastern Time

4

## 5 NEW HOPE FOR MILLIONS OF AMERICANS SUFFERING FROM 6 PERSISTENT

7 **The fear of addiction is exaggerated.**

8 One cause of patient resistance to appropriate pain treatment – the  
9 fear of addiction – is largely unfounded. According to Dr. Max,  
10 "Experts agree that most pain caused by surgery or cancer can be  
11 relieved, primarily by carefully adjusting the dose of opioid  
12 (narcotic) pain reliever to each patient's need, and that there is very  
13 little risk of addiction from the proper uses of these drugs for pain  
14 relief."

15 Paul D. Goldenheim, M.D., Vice President of **Purdue Pharma** L.P. in  
16 Norwalk, Connecticut, agrees with this assessment. "Proper use of  
17 medication is an essential weapon in the battle against persistent  
18 pain. But too often fear, misinformation and poor communication stand  
19 in the way of their legitimate use."

20 223. Dr. Portenoy, the Purdue KOL mentioned previously, also stated in a promotional  
21 video from the 1990s that "the likelihood that the treatment of pain using an opioid drug which is  
22 prescribed by a doctor will lead to addiction is extremely low."<sup>113</sup>



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<sup>113</sup> Catan and Perez, *supra* note 89.

1       224. Purdue also specifically used the Porter and Jick letter in its 1998 promotional  
 2 video, "I got my life back," in which Dr. Alan Spanos says, "In fact, the rate of addiction  
 3 amongst pain patients who are treated by doctors is *much less than 1%*."<sup>114</sup>



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 10     225. The Porter and Jick letter was also used on Purdue's "Partners Against Pain"  
 11 website, which was available in the early 2000s, where Purdue claimed that the addiction risk  
 12 with OxyContin was very low.<sup>115</sup>  
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 14

15     226. The Porter and Jick letter was used frequently in literature given to prescribing  
 16 physicians and to patients who were prescribed OxyContin.<sup>116</sup>  
 17  
 18

19     227. In addition to the Porter and Jick letter, the Manufacturing Defendants  
 20 exaggerated the significance of a study published in 1986 regarding cancer patients treated with  
 21 opioids. Conducted by Dr. Portenoy and another pain specialist, Dr. Kathleen Foley, the study  
 22 involved only 38 patients, who were treated for non-malignant cancer pain with low doses of  
 23 opioids (the majority were given less than 20 MME/day, the equivalent of only 13 mg of  
 24  
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24<sup>114</sup> Our Amazing World, *Purdue Pharma OxyContin Commercial*, <https://www.youtube.com/watch?v=Er78Dj5hyel> (last visited Mar. 22, 2018) (emphasis added).

25<sup>115</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 65.

26<sup>116</sup> Art Van Zee, M.D., *The OxyContin Abuse Problem: Spotlight on Purdue Pharma's Marketing* (Aug. 22, 2001), <https://web.archive.org/web/20170212210143/https://www.fda.gov/ohrms/dockets/dockets/01n0256/c000297-A.pdf>.

1 oxycodone).<sup>117</sup> Of these thirty-eight patients, only two developed problems with opioid abuse,  
 2 and Dr. Portenoy and Dr. Foley concluded that “opioid maintenance therapy can be a safe,  
 3 salutary and more humane alternative to the options of surgery or no treatment in those patients  
 4 with intractable non-malignant pain and no history of drug abuse.”<sup>118</sup> Notwithstanding the small  
 5 sample size, low doses of opioids involved, and the fact that all the patients were cancer patients,  
 6 the Manufacturing Defendants used this study as “evidence” that high doses of opioids were safe  
 7 for the treatment of chronic non-cancer pain.

8       228. The Manufacturing Defendants’ repeated misrepresentations about the low risk of  
 9 opioid addiction were so effective that this concept became part of the conventional wisdom. Dr.  
 10 Nathaniel Katz, a pain specialist, recalls learning in medical school that previous fears about  
 11 addiction were misguided, and that doctors should feel free to allow their patients the pain relief  
 12 that opioids can provide. He did not question this until one of his patients died from an overdose.  
 13 Then, he searched the medical literature for evidence of the safety and efficacy of opioid  
 14 treatment for chronic pain. “There’s not a shred of research on the issue. All these so-called  
 15 experts in pain are dedicated and have been training me that opioids aren’t as addictive as we  
 16 thought. But what is that based on? It was based on nothing.”<sup>119</sup>

17       229. At a hearing before the House of Representatives’ Subcommittee on Oversight  
 18 and Investigations of the Committee on Energy and Commerce in August 2001, Purdue  
 19 continued to emphasize “legitimate” treatment, dismissing cases of overdose and death as  
 20 something that would not befall “legitimate” patients: “Virtually all of these reports involve  
 21 people who are abusing the medication, not patients with legitimate medical needs under the  
 22 treatment of a healthcare professional.”<sup>120</sup>

23  
 24 <sup>117</sup> Russell K. Portenoy and Kathleen M. Foley, *Chronic Use of Opioid Analgesics in Non-Malignant Pain: Report*  
   of 38 Cases, 25 Pain 171-86 (1986), <https://www.ncbi.nlm.nih.gov/pubmed/2873550>.

25 <sup>118</sup> *Id.*

26 <sup>119</sup> Quinones, *supra* note 45, at 188-89.

<sup>120</sup> *Oxycontin: Its Use and Abuse: Hearing Before the H. Subcomm. on Oversight and Investigations of the Comm. on Energy and Commerce*, 107th Cong. 1 (Aug. 28, 2001) (statement of Michael Friedman, Executive Vice

1       230. Purdue spun this baseless “legitimate use” distinction out even further in a patient  
 2 brochure about OxyContin, called “A Guide to Your New Pain Medicine and How to Become a  
 3 Partner Against Pain.” In response to the question, “Aren’t opioid pain medications like  
 4 OxyContin Tablets ‘addicting’? Even my family is concerned about this,” Purdue claimed that  
 5 there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes:

6           Drug addiction means using a drug to get “high” rather than to relieve pain. You  
 7 are taking opioid pain medication for medical purposes. The medical purposes are  
 clear and the effects are beneficial, not harmful.

8       231. Similarly, Dr. David Haddox, Senior Medical Director for Purdue, cavalierly  
 9 stated, “[w]hen this medicine is used appropriately to treat pain under a doctor’s care, it is not  
 10 only effective, it is safe.”<sup>121</sup> He went so far as to compare OxyContin to celery, because even  
 11 celery would be harmful if injected: “If I gave you a stalk of celery and you ate that, it would be  
 12 healthy for you. But if you put it in a blender and tried to shoot it into your veins, it would not be  
 13 good.”<sup>122</sup>

14       232. Purdue sales representatives also repeated these misstatements regarding the low  
 15 risk for addiction to doctors across the country.<sup>123</sup> Its sales representatives targeted primary care  
 16 physicians in particular, downplaying the risk of addiction and, as one doctor observed,  
 17 “promot[ing] among primary care physicians a more liberal use of opioids.”<sup>124</sup>

18       233. Purdue sales representatives were instructed to “distinguish between iatrogenic  
 19 addiction (<1% of patients) and substance abusers/diversion (about 10% of the population abuse  
 20 something: weed; cocaine; heroin; alcohol; valium; etc.).”<sup>125</sup>

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23           President, Chief Operating Officer, Purdue Pharma, L.P.), <https://www.gpo.gov/fdsys/pkg/CHRG-107hrg75754/html/CHRG-107hrg75754.htm>.

24       <sup>121</sup> Roger Alford, *Deadly OxyContin abuse expected to spread in the U.S.*, Charleston Gazette, Feb. 9, 2001.

25       <sup>122</sup> *Id.*

26       <sup>123</sup> Barry Meier, *In Guilty Plea, OxyContin Maker to Pay \$600 Million*, New York Times (May 10, 2007), <http://www.nytimes.com/2007/05/10/business/11drug-web.html>.

<sup>124</sup> Van Zee, *The Promotion and Marketing of OxyContin*, *supra* note 65.

<sup>125</sup> Meier, *supra* note 17, at 269.

1       234. Purdue also marketed OxyContin for a wide variety of conditions and to doctors  
 2 who were not adequately trained in pain management.<sup>126</sup>

3       235. As of 2003, Purdue's Patient Information guide for OxyContin contained the  
 4 following language regarding addiction:

5              Concerns about abuse, addiction, and diversion should not prevent the proper management of pain.  
 6              The development of addiction to opioid analgesics in properly managed patients with pain has been  
 7              reported to be rare. However, data are not available to establish the true incidence of addiction in  
 chronic pain patients.

8       236. Although Purdue has acknowledged it has made some misrepresentations about  
 9 the safety of its opioids,<sup>127</sup> it has done nothing to address the ongoing harms of their  
 10 misrepresentations; in fact, it continues to make those misrepresentations today.

11       237. Defendant Endo also made dubious claims about the low risk of addiction. For  
 12 instance, it sponsored a website, PainKnowledge.com, on which in 2009 it claimed that “[p]eople  
 13 who take opioids as prescribed usually do not become addicted.”<sup>128</sup> The website has since been  
 14 taken down.

15       238. In another website, PainAction.com—which is still currently available today—  
 16 Endo also claimed that “most chronic pain patients do not become addicted to the opioid  
 17 medications that are prescribed for them.”<sup>129</sup>

21       

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<sup>126</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 32.

22       <sup>127</sup> Following the conviction in 2007 of three of its executives for misbranding OxyContin, Purdue released a  
 23 statement in which they acknowledged their false statements. “Nearly six years and longer ago, some employees  
 24 made, or told other employees to make, certain statements about OxyContin to some health care professionals that  
 25 were inconsistent with the F.D.A.-approved prescribing information for OxyContin and the express warnings it  
 26 contained about risks associated with the medicine. The statements also violated written company policies  
 requiring adherence to the prescribing information.”

<sup>128</sup> German Lopez, *The growing number of lawsuits against opioid companies, explained*, Vox (Feb. 27, 2018,  
 2:25pm), <https://www.vox.com/policy-and-politics/2017/6/7/15724054/opioid-companies-epidemic-lawsuits>.

<sup>129</sup> *Opioid medication and addiction*, Pain Action (Aug. 17, 2017), <https://www.painaction.com/opioid-medication-addiction/>.

1       239. In a pamphlet titled “Understanding Your Pain: Taking Oral Opioid Analgesics,”  
 2 Endo assured patients that addiction is something that happens to people who take opioids for  
 3 reasons other than pain relief, “such as unbearable emotional problems”<sup>130</sup>:

4              *Some questions you may have are:*

5              *Is it wrong to take opioids for pain?*

- 6              ◆ No. Pain relief is an important medical  
                   reason to take opioids as prescribed  
                   by your doctor. Addicts take opioids  
                   for other reasons, such as unbearable  
                   emotional problems. Taking opioids as  
                   prescribed for pain relief is not addiction.

9              *How can I be sure I'm not addicted?*

- 10             ◆ Addiction to an opioid would mean that  
                   your pain has gone away but you still  
                   take the medicine regularly when you  
                   don't need it for pain, maybe just to  
                   escape from your problems.
- 11             ◆ Ask yourself: Would I want to take this  
                   medicine if my pain went away? If you  
                   answer no, you are taking opioids for  
                   the right reasons—to relieve your pain  
                   and improve your function. You are not  
                   addicted.

18       240. In addition, Endo made statements in pamphlets and publications that most health  
 19 care providers who treat people with pain agree that most people do not develop an addiction  
 20 problem. These statements also appeared on websites sponsored by Endo, such as Opana.com.

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 22  
 23  
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 25  
 26       <sup>130</sup> *Understanding Your Pain: Taking Oral Opioid Analgesics*, Endo Pharm. (2004),  
                  [http://www.thblack.com/links/RSD/Understand\\_Pain\\_Opioid\\_Analgesics.pdf](http://www.thblack.com/links/RSD/Understand_Pain_Opioid_Analgesics.pdf).

1       241. In its currently active website, PrescribeResponsibly.com, Defendant Janssen  
 2 states that concerns about opioid addiction are “overestimated” and that “true addiction occurs  
 3 only in a small percentage of patients.”<sup>131</sup>

4

## 5                              Use of Opioid Analgesics in 6                              Pain Management



14                              *Other Opioid Analgesic Concerns*

15        Aside from medical issues related to opioid analgesics, there are nonmedical  
 16        issues that may have an impact on prescribing patterns and patient use of  
 17        these drugs. Practitioners are often concerned about prescribing opioid  
 18        analgesics due to potential legal issues and questions of addiction.<sup>15,16</sup> By  
 19        the same token, patients report similar concerns about developing an  
 20        addiction to opioid analgesics.<sup>17</sup> While these concerns are not without some  
 21        merit, it would appear that they are often overestimated. According to clinical  
 22        opinion polls, true addiction occurs only in a small percentage of patients  
 23        with chronic pain who receive chronic opioid analgesics analgesic therapy.<sup>18</sup>



26       242. Similarly, in a 2009 patient education video titled “Finding Relief: Pain  
 27       Management for Older Adults,” Janssen sponsored a video by the American Academy of Pain  
 28

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29       131 Keith Candiotti, M.D., *Use of Opioid Analgesics in Pain Management*, Prescribe Responsibly,  
 30       <http://www.prescriberesponsibly.com/articles/opioid-pain-management> (last modified July 2, 2015).

1 Medicine that indicated that opioids are rarely addictive. The video has since been taken  
 2 down.<sup>132</sup>

3       243. Janssen also approved and distributed a patient education guide in 2009 that  
 4 attempted to counter the “myth” that opioids are addictive, claiming that “[m]any studies show  
 5 that opioids are rarely addictive when used properly for the management of chronic pain.”<sup>133</sup>

6       244. In addition, all the Manufacturing Defendants used third parties and front groups  
 7 to further their false and misleading statements about the safety of opioids.

8       245. For example, in testimony for the Hearing to Examine the Effects of the Painkiller  
 9 OxyContin, Focusing on Risks and Benefits, in front of the Senate Health, Education, Labor and  
 10 Pensions Committee in February 2002, Dr. John D. Giglio, Executive Director of the APF, the  
 11 organization which, as described above, received the majority of its funding from opioid  
 12 manufacturers, including Purdue, stated that “opioids are safe and effective, and only in rare  
 13 cases lead to addiction.”<sup>134</sup> Along with Dr. Giglio’s testimony, the APF submitted a short  
 14 background sheet on “the scope of the undertreatment of pain in the U.S.,” which asserted that  
 15 “opioids are often the best” treatment for pain that hasn’t responded to other techniques, but that  
 16 patients and many doctors “lack even basic knowledge about these options and fear that powerful  
 17 pain drugs will [c]ause addiction.” According to the APF, “most studies show that less than 1%  
 18 of patients become addicted, which is medically different from becoming physically  
 19 dependent.”<sup>135</sup>

20       246. The APF further backed up Purdue in an amicus curiae brief filed in an Ohio  
 21 appeals court in December 2002, in which it claimed that “medical leaders have come to  
 22

23       <sup>132</sup> Molly Huff, *Finding Relief: Pain Management for Older Adults*, Ctrs. for Pain Mgmt. (Mar. 9, 2011),  
 24       <http://www.managepaintoday.com/news/-Finding-Relief-Pain-Management-for-Older-Adults>.

25       <sup>133</sup> Lopez, *supra* note 128.

26       <sup>134</sup> *Oxycontin: Balancing Risks and Benefits: Hearing of the S. Comm. on Health, Education, Labor and Pensions*,  
 107th Cong. 2 (Feb. 12, 2002) (testimony of John D. Giglio, M.A., J.D., Executive Director, American Pain  
 Foundation), <https://www.help.senate.gov/imo/media/doc/Giglio.pdf>.

<sup>135</sup> *Id.*

1 understand that the small risk of abuse does not justify the withholding of these highly effective  
 2 analgesics from chronic pain patients.”<sup>136</sup>

3       247. In a 2007 publication titled “Treatment Options: A Guide for People Living with  
 4 Pain,” APF downplayed the risk of addiction and argued that concern about this risk should not  
 5 prevent people from taking opioids: “Restricting access to the most effective medications for  
 6 treating pain is not the solution to drug abuse or addiction.”<sup>137</sup> APF also tried to normalize the  
 7 dangers of opioids by listing opioids as one of several “[c]ommon drugs that can cause physical  
 8 dependence,” including steroids, certain heart medications, and caffeine.<sup>138</sup>

9       248. The Manufacturing Defendants’ repeated statements about the low risk of  
 10 addiction when taking opioids as prescribed for chronic pain were blatantly false and were made  
 11 with reckless disregard for the potential consequences.

12       **2. The Manufacturing Defendants falsely claimed that opioids were proven  
 13 effective for chronic pain and would improve quality of life.**

14       249. Not only did the Manufacturing Defendants falsely claim that the risk of addiction  
 15 to prescription opioids was low, these Defendants represented that there was a significant upside  
 16 to long-term opioid use, including that opioids could restore function and improve quality of  
 17 life.<sup>139</sup>

18       250. Such claims were viewed as a critical part of the Manufacturing Defendants’  
 19 marketing strategies. For example, an internal Purdue report from 2001 noted the lack of data  
 20 supporting improvement in quality of life with OxyContin treatment:

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21  
 22       <sup>136</sup> Brief Amici Curiae of American Pain Foundation, National Foundation for the Treatment of Pain, and The Ohio  
 23 Pain Initiative, in Support of Defendants/Appellants, *Howland v. Purdue Pharma, L.P.*, Appeal No. CA 2002 09  
 0220 (Butler Co., Ohio 12th Court of Appeals, Dec. 23, 2002), <https://ia801005.us.archive.org/23/items/279014-howland-apf-amicus/279014-howland-apf-amicus.pdf>.

24       <sup>137</sup> *Treatment Options: A Guide for People Living with Pain*, Am. Pain Found.,  
 25 <https://assets.documentcloud.org/documents/277605/apf-treatmentoptions.pdf> (last visited Mar. 22, 2018).

26       <sup>138</sup> *Id.*

27       <sup>139</sup> This case *does not* request or require the Court to specifically adjudicate whether opioids are appropriate for the  
 28 treatment of chronic, non-cancer pain—though the scientific evidence strongly suggests they are not.

1 Janssen has been stressing decreased side effects, especially constipation, as well  
 2 as patient quality of life, as supported by patient rating compared to sustained  
 3 release morphine . . . We do not have such data to support OxyContin promotion. . .  
 4 . . In addition, Janssen has been using the “life uninterrupted” message in promotion  
 5 of Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less  
 6 about their pain.” This is a competitive advantage based on our inability to make  
 7 any quality of life claims.<sup>140</sup>

8       251. Despite the lack of data supporting improvement in quality of life, Purdue ran a  
 9 full-page ad for OxyContin in the Journal of the American Medical Association in 2002,  
 10 proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside  
 11 his grandson.<sup>141</sup> This ad earned a warning letter from the FDA, which admonished, “It is  
 12 particularly disturbing that your November ad would tout ‘Life With Relief’ yet fail to warn that  
 13 patients can die from taking OxyContin.”<sup>142</sup>

14       252. Purdue also consistently tried to steer any concern away from addiction and focus  
 15 on its false claims that opioids were effective and safe for treating chronic pain. At a hearing  
 16 before the House of Representatives’ Subcommittee on Oversight and Investigations of the  
 17 Committee on Energy and Commerce in August 2001, Michael Friedman, Executive Vice  
 18 President and Chief Operating Officer of Purdue, testified that “even the most vocal critics of  
 19 opioid therapy concede the value of OxyContin in the legitimate treatment of pain,” and that  
 20 “OxyContin has proven itself an effective weapon in the fight against pain, returning many  
 21 patients to their families, to their work, and to their ability to enjoy life.”<sup>143</sup>

22       253. Purdue sponsored the development and distribution of an APF guide in 2011  
 23 which claimed that “multiple clinical studies have shown that opioids are effective in improving  
 24 daily function, psychological health, and health-related quality of life for chronic pain patients.”  
 25 This guide is still available today.

26<sup>140</sup> Meier, *supra* note 17, at 281.

<sup>141</sup> *Id.* at 280.

<sup>142</sup> Chris Adams, *FDA Orders Purdue Pharma To Pull Its OxyContin Ads*, Wall Street Journal (Jan. 23, 2003,  
 27 12:01am), <https://www.wsj.com/articles/SB1043259665976915824>.

<sup>143</sup> *Oxycontin: Its Use and Abuse*, *supra* note 120.

1       254. Purdue also ran a series of advertisements of OxyContin in 2012 in medical  
 2 journals titled “Pain vignettes,” which were styled as case studies of patients with persistent pain  
 3 conditions and for whom OxyContin was recommended to improve their function.

4       255. Purdue and Endo also sponsored and distributed a book in 2007 to promote the  
 5 claim that pain relief from opioids, by itself, improved patients’ function. The book remains for  
 6 sale online today.

7       256. Endo’s advertisements for Opana ER claimed that use of the drug for chronic pain  
 8 allowed patients to perform demanding tasks like construction and portrayed Opana ER users as  
 9 healthy and unimpaired.

10      257. Endo’s National Initiative on Pain Control (NIPC) website also claimed in 2009  
 11 that with opioids, “your level of function should improve; you may find you are now able to  
 12 participate in activities of daily living, such as work and hobbies, that you were not able to enjoy  
 13 when your pain was worse.”

14      258. Endo further sponsored a series of CME programs through NIPC which claimed  
 15 that chronic opioid therapy has been “shown to reduce pain and depressive symptoms and  
 16 cognitive functioning.”

17      259. Through PainKnowledge.org, Endo also supported and sponsored guidelines that  
 18 stated, among other things, that “Opioid Medications are a powerful and often highly effective  
 19 tool in treating pain,” and that “they can help restore comfort, function, and quality of life.”<sup>144</sup>

20      260. In addition, Janssen sponsored and edited patient guides which stated that  
 21 “opioids may make it easier for people to live normally.” The guides listed expected functional  
 22 improvements from opioid use, including sleeping through the night, and returning to work,  
 23 recreation, sex, walking, and climbing stairs.

24  
 25  
 26      

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<sup>144</sup>*Informed Consent for Using Opioids to Treat Pain*, Painknowledge.org (2007),  
[https://www.mainequalitycounts.org/image\\_upload/Opioid%20Informed%20Consent%20Formatted\\_1\\_23\\_2008.pdf](https://www.mainequalitycounts.org/image_upload/Opioid%20Informed%20Consent%20Formatted_1_23_2008.pdf).

1       261. Janssen also sponsored, funded, and edited a website which featured an interview  
 2 edited by Janssen that described how opioids allowed a patient to “continue to function.” This  
 3 video is still available today.

4       262. Furthermore, sales representatives for the Manufacturing Defendants  
 5 communicated and continue to communicate the message that opioids will improve patients’  
 6 function, without appropriate disclaimers.

7       263. The Manufacturing Defendants’ statements regarding opioids’ ability to improve  
 8 function and quality of life are false and misleading. As the CDC’s *Guideline for Prescribing*  
 9 *Opioids for Chronic Pain* (the “2016 CDC Guideline” or “Guideline”)<sup>145</sup> confirms, not a single  
 10 study supports these claims.

11       264. In fact, to date, there have been no long-term studies that demonstrate that opioids  
 12 are effective for treating long-term or chronic pain. Instead, reliable sources of information,  
 13 including from the CDC in 2016, indicate that there is “[n]o evidence” to show “a long-term  
 14 benefit of opioids in pain and function versus no opioids for chronic pain.”<sup>146</sup> By contrast,  
 15 significant research has demonstrated the colossal dangers of opioids. The CDC, for example,  
 16 concluded that “[e]xtensive evidence shows the possible harms of opioids (including opioid use  
 17 disorder, overdose, and motor vehicle injury)” and that “[o]pioid pain medication use presents  
 18 serious risks, including overdose and opioid use disorder.”<sup>147</sup>

19       **3. The Manufacturing Defendants falsely claimed doctors and patients could  
 20 increase opioid usage indefinitely without added risk.**

21       265. The Manufacturing Defendants also made false and misleading statements  
 22 claiming that there is no dosage ceiling for opioid treatment. These misrepresentations were  
 23 integral to the Manufacturing Defendants’ promotion of prescription opioids for two reasons.  
 24 First, the idea that there was no upward limit was necessary for the overarching deception that

25       <sup>145</sup> 2016 CDC Guideline, *supra* note 33.  
 26       <sup>146</sup> *Id.*  
       <sup>147</sup> *Id.*

1      opioids are appropriate treatment for chronic pain. As discussed above, people develop a  
 2      tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly  
 3      increasing the dose. Second, the dosing misrepresentation was necessary for the claim that  
 4      OxyContin and competitor drugs allowed 12-hour dosing.

5            266.     Twelve-hour dosing is a significant marketing advantage for any medication,  
 6      because patient compliance is improved when a medication only needs to be taken twice a day.  
 7      For prescription painkillers, the 12-hour dosing is even more significant because shorter-acting  
 8      painkillers did not allow patients to get a full night's sleep before the medication wore off. A  
 9      Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is  
 10     'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'"  
 11     and further that "[t]he convenience of q12h dosing was emphasized as the most important  
 12     benefit."<sup>148</sup>

13           267.     Purdue executives therefore maintained the messaging of 12-hour dosing even  
 14     when many reports surfaced that OxyContin did not last 12 hours. Instead of acknowledging a  
 15     need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills.

16           268.     For example, in a 1996 sales strategy memo from a Purdue regional manager, the  
 17     manager emphasized that representatives should "convinc[e] the physician that there is no need"  
 18     for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and  
 19     instead the solution is prescribing higher doses. The manager directed representatives to discuss  
 20     with physicians that there is "no[] upward limit" for dosing and ask "if there are any reservations  
 21     in using a dose of 240mg-320mg of OxyContin."<sup>149</sup>

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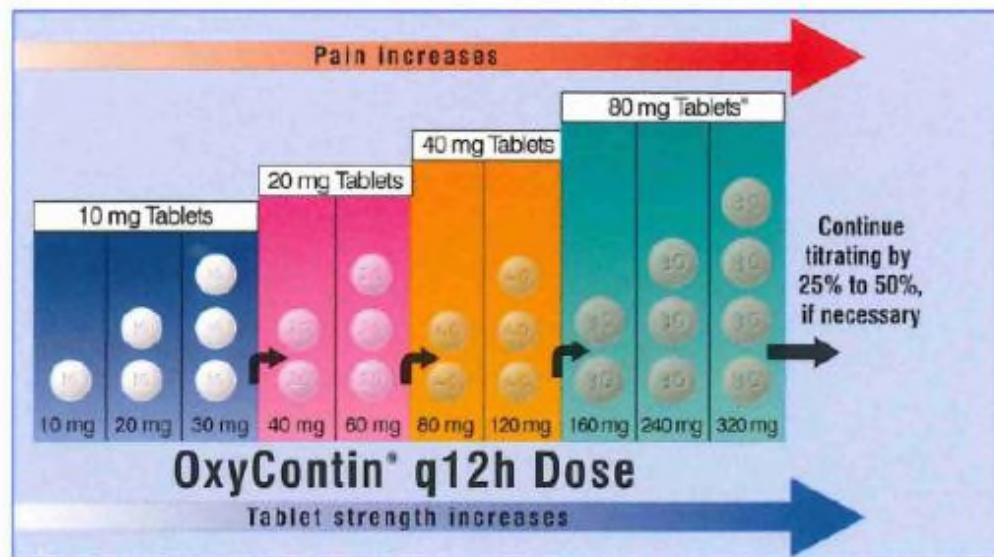
25                  <sup>148</sup> *OxyContin launch*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/oxycontin-launch-1995/>.

26                  <sup>149</sup> *Sales manager on 12-hour dosing*, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/sales-manager-on12-hour-dosing-1996/>.

1       269. As doctors began prescribing OxyContin at shorter intervals in the late 1990s,  
 2 Purdue directed its sales representatives to “refocus” physicians on 12-hour dosing. One sales  
 3 manager instructed her team that anything shorter “needs to be nipped in the bud. NOW!!”<sup>150</sup>

4       270. These misrepresentations were incredibly dangerous. As noted above, opioid  
 5 dosages at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50  
 6 MME is equal to just 33 mg of oxycodone. Notwithstanding the risks, the 2003 Conversion  
 7 Guide for OxyContin contained the following diagram for increasing dosage up to 320 mg:

8 **A Guide to Titration of OxyContin®**



18       271. In a 2004 response letter to the FDA, Purdue tried to address concerns that  
 19 patients who took OxyContin more frequently than 12 hours would be at greater risk of side  
 20 effects or adverse reactions. Purdue contended that the peak plasma concentrations of oxycodone  
 21 would not increase with more frequent dosing, and therefore no adjustments to the package  
 22 labeling or 12-hour dosing regimen were needed.<sup>151</sup> But these claims were false, and Purdue’s  
 23  
 24

25       <sup>150</sup> Harriet Ryan, Lisa Girion, and Scott Glover, ‘*You Want a Description of Hell?*’ *OxyContin’s 12-Hour Problem*  
 26       (May 5, 2016), <http://www.latimes.com/projects/oxycontin-part1/>.

<sup>151</sup> *Purdue Response to FDA*, 2004, Los Angeles Times (May 5, 2016), <http://documents.latimes.com/purdue-response-fda-2004/>.

1 suggestion that there was no upper limit or risk associated with increased dosage was incredibly  
 2 misleading.

3       272. Suggesting that it recognized the danger of its misrepresentations of no dose  
 4 ceiling, Purdue discontinued the OxyContin 160 mg tablet in 2007 and stated that this step was  
 5 taken “to reduce the risk of overdose accompanying the abuse of this dosage strength.”<sup>152</sup>

6       273. But still Purdue and the other Manufacturing Defendants worked hard to protect  
 7 their story. In March 2007, Dr. Gary Franklin, Medical Director for the Washington State  
 8 Department of Labor & Industries, published the *Interagency Guideline on Opioid Dosing for*  
 9 *Chronic Non-Cancer Pain*. Developed in collaboration with providers in Washington State who  
 10 had extensive experience in the evaluation and treatment of patients with chronic pain, the  
 11 guideline recommended a maximum daily dose of opioids to protect patients.

12       274. In response, Purdue sent correspondence to Dr. Franklin specifically indicating,  
 13 among other things, that “limiting access to opioids for persons with chronic pain is not the  
 14 answer” and that the “safety and efficacy of OxyContin doses greater than 40 mg every 12 hours  
 15 in patients with chronic nonmalignant pain” was well established. Purdue even went so far as to  
 16 represent to Dr. Franklin that even if opioid treatment produces significant adverse effects in a  
 17 patient, “this does not preclude a trial of another opioid.”

18       275. In 2010, Purdue published a Risk Evaluation and Mitigation Strategy (“REMS”)  
 19 for OxyContin, but even the REMS does not address concerns with increasing dosage, and  
 20 instead advises prescribers that “dose adjustments may be made every 1-2 days”; “it is most  
 21 appropriate to increase the q12h dose”; the “total daily dose can usually be increased by 25% to

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26       <sup>152</sup> *OxyContin Tablets Risk Management Program*, Purdue Pharma L.P.,  
<https://web.archive.org/web/20170215064438/https://www.fda.gov/ohrms/dockets/DOCKETS/07p0232/07p-0232-cp00001-03-Exhibit-02-Part-1-vol1.pdf> (revised May 18, 2007).

1 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under  
 2 control, then resume upward titration.”<sup>153</sup>

3 276. In 2012, APF claimed on its website that there was no “ceiling dose” for opioids  
 4 for chronic pain.<sup>154</sup> APF also made this claim in a guide sponsored by Purdue, which is still  
 5 available online.

6 277. Accordingly, Purdue continued to represent both publicly and privately that  
 7 increased opioid usage was safe and did not present additional risk at higher doses.

8 278. Janssen also made the same misrepresentations regarding the disadvantages of  
 9 dosage limits for other pain medicines in a 2009 patient education guide, while failing to address  
 10 the risks of dosage increases with opioids.

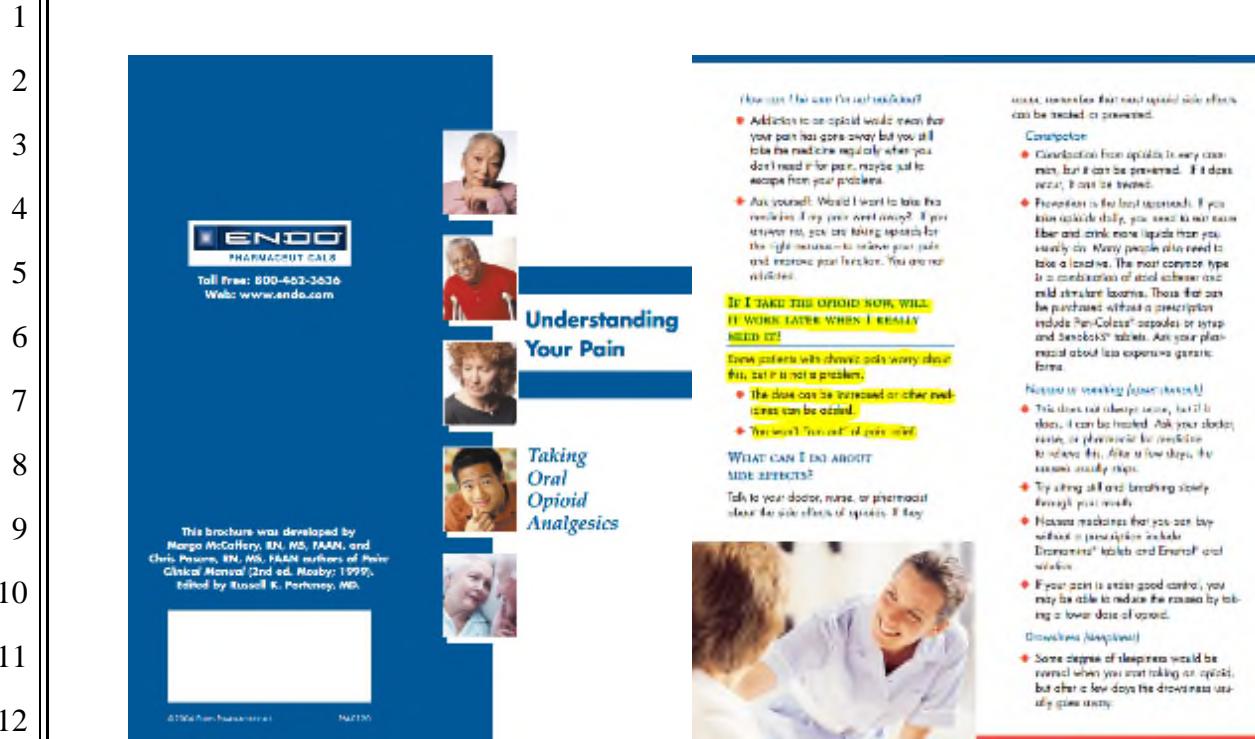
11 279. Endo, on a website it sponsors, PainKnowledge.com, also made the claim in 2009  
 12 that opioid dosages could be increased indefinitely.

13 280. In the “Understanding Your Pain” pamphlet discussed above, Endo assures opioid  
 14 users that concern about developing tolerance to the drugs’ pain-relieving effect is “not a  
 15 problem,” and that “[t]he dose can be increased” and “[y]ou won’t ‘run out’ of pain relief.”<sup>155</sup>  
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<sup>153</sup> *OxyContin Risk Evaluation and Mitigation Strategy*, Purdue Pharma L.P.,  
<https://web.archive.org/web/20170215190303/https://www.fda.gov/downloads/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/UCM220990.pdf> (last modified Nov. 2010).

<sup>154</sup> Noah Nesin, M.D., FAAFP, *Responsible Opioid Prescribing*, PCHC  
[https://www.mainequalitycounts.org/image\\_upload/Keynote%20Managing%20Chronic%20Pain%20and%20Opioids\\_Nesin.pdf](https://www.mainequalitycounts.org/image_upload/Keynote%20Managing%20Chronic%20Pain%20and%20Opioids_Nesin.pdf) (last visited Mar. 22, 2018).

<sup>155</sup> *Understanding Your Pain: Taking Oral Opioid Analgesics*, *supra* note 130.



281. Dosage limits with respect to opioids are particularly important not only because of the risk of addiction but also because of the potentially fatal side effect of respiratory depression. Endo's "Understanding Your Pain" pamphlet minimized this serious side effect, calling it "slowed breathing," declaring that it is "very rare" when opioids are used "appropriately," and never stating that it could be fatal:

### *"Slowed breathing"*

- ◆ The medical term for "slowed breathing" is "respiratory depression."
- ◆ This is very rare when oral opioids are used appropriately for pain relief.
- ◆ If you become so sleepy that you cannot make yourself stay awake, you may be in danger of slowed breathing. Stop taking your opioid and call your doctor immediately.

1           **4. The Manufacturing Defendants falsely instructed doctors and patients that  
2 more opioids were the solution when patients presented symptoms of  
3 addiction.**

4       282. Not only did the Manufacturing Defendants hide the serious risks of addiction  
5 associated with opioids, they actively worked to prevent doctors from taking steps to prevent or  
6 address opioid addiction in their patients.

7       283. One way that the Manufacturing Defendants worked to obstruct appropriate  
8 responses to opioid addiction was to push a concept called “pseudoaddiction.” Dr. David  
9 Haddox—who later became a Senior Medical Director for Purdue—published a study in 1989  
10 coining the term, which he characterized as “the iatrogenic syndrome of abnormal behavior  
11 developing as a direct consequence of inadequate pain management.”<sup>156</sup> (“Iatrogenic” describes a  
12 condition induced by medical treatment.) In other words, he claimed that people on prescription  
13 opioids who exhibited classic signs of addiction—“abnormal behavior”—were not addicted, but  
14 rather simply suffering from under-treatment of their pain. His solution for pseudoaddiction?  
More opioids.

15      284. Although this concept was formed based on a single case study, it proved to be a  
16 favorite trope in the Manufacturing Defendants’ marketing schemes. For example, using this  
17 study, Purdue informed doctors and patients that signs of addiction are actually the signs of  
18 under-treated pain which should be treated with even more opioids. Purdue reassured doctors and  
19 patients, telling them that “chronic pain has been historically undertreated.”<sup>157</sup>

20      285. The Manufacturing Defendants continued to spread the concept of  
21 pseudoaddiction through the APF, which even went so far as to compare opioid addicts to coffee  
22 drinkers. In a 2002 court filing, APF wrote that “[m]any pain patients (like daily coffee drinkers)  
23 claim they are ‘addicted’ when they experience withdrawal symptoms associated with physical  
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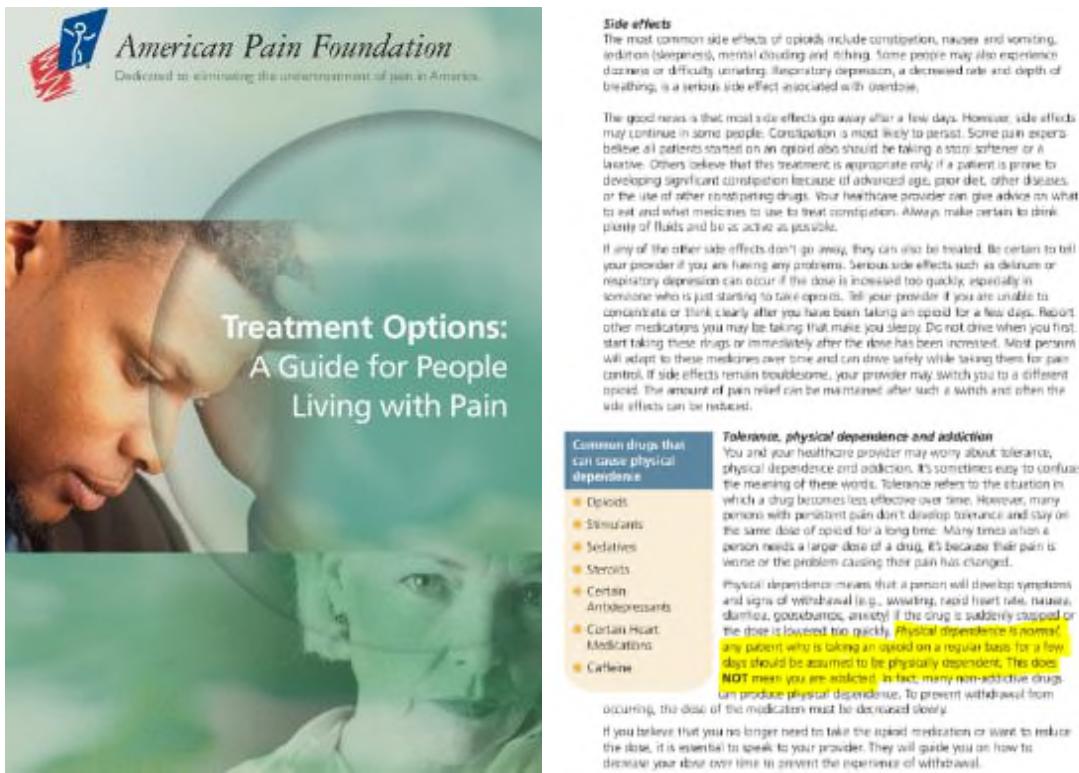
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25           <sup>156</sup> David E. Weissman and J. David Haddox, *Opioid pseudoaddiction--an iatrogenic syndrome*, 36(3) Pain 363-66  
26           (Mar. 1989), <https://www.ncbi.nlm.nih.gov/pubmed/2710565>.

157 *Oxycontin: Its Use and Abuse*, *supra* note 120.

1 dependence as they decrease their dose. But unlike actual addicts, such individuals, if they  
 2 resume their opioid use, will only take enough medication to alleviate their pain . . .”<sup>158</sup>

3       286. In a 2007 publication titled “Treatment Options: A Guide for People Living with  
 4 Pain,” the APF claimed: “*Physical dependence is normal*; any patient who is taking an opioid on  
 5 a regular basis for a few days should be assumed to be physically dependent. This does **NOT**  
 6 mean you are addicted.”<sup>159</sup> In this same publication, when describing behaviors of addiction, the  
 7 APF again used the idea of pseudoaddiction, claiming that people who are not substance abusers  
 8 may also engage in behaviors that mirror those of actual addicts.



21       287. Purdue published a REMS for OxyContin in 2010, and in the associated  
 22 Healthcare Provider Training Guide stated that “[b]ehaviors that suggest drug abuse exist on a  
 23 continuum, and pain-relief seeking behavior can be mistaken for drug-seeking behavior.”<sup>160</sup>

25       158 APF Brief Amici Curiae, *supra* note 136, at 10-11.

26       159 *Treatment Options: A Guide for People Living with Pain*, *supra* note 137.

160 *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 153.

1       288. Purdue worked, and continues to work, to create confusion about what addiction  
 2 is. For example, Purdue continues to emphasize that abuse and addiction are separate and distinct  
 3 from physical dependence. Regardless of whether these statements may be technically correct,  
 4 they continue to add ambiguity over the risks and benefits of opioids.

5       289. Endo sponsored an NIPC CME program in 2009 which promoted the concept of  
 6 pseudoaddiction by teaching that a patient's aberrant behavior was the result of untreated pain.  
 7 Endo substantially controlled NIPC by funding its projects, developing content, and reviewing  
 8 NIPC materials.

9       290. A 2001 paper which was authored by a doctor affiliated with Janssen stated that  
 10 "[m]any patients presenting to a doctor's office asking for pain medications are accused of drug  
 11 seeking. In reality, most of these patients may be undertreated for their pain syndrome."<sup>161</sup>

12       291. In 2009, on a website it sponsored, Janssen stated that pseudoaddiction is different  
 13 from true addiction "because such behaviors can be resolved with effective pain  
 14 management."<sup>162</sup>

15       292. Indeed, on its currently active website PrescribeResponsibly.com, Janssen defines  
 16 pseudoaddiction as "a syndrome that causes patients to seek additional medications due to

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24       <sup>161</sup> Howard A. Heit, MD, FACP, FASAM, *The truth about pain management: the difference between a pain patient*  
 25       *and an addicted patient*, 5 European Journal of Pain 27-29 (2001),  
<http://www.med.uottawa.ca/courses/totalpain/pdf/doc-34.pdf>.

26       <sup>162</sup> Chris Morran, *Ohio: Makers Of OxyContin, Percocet & Other Opioids Helped Fuel Drug Epidemic By*  
 Misleading Doctors, Patients, Consumerist (May 31, 2017, 2:05pm), <https://consumerist.com/2017/05/31/ohio-makers-of-oxycontin-percocet-other-opioids-helped-fuel-drug-epidemic-by-misleading-doctors-patients/>.

inadequate pharmacotherapy being prescribed. Typically, when the pain is treated appropriately, the inappropriate behavior ceases.”<sup>163</sup>

## What a Prescriber Should Know Before Writing the First Prescription



TABLE 1: Definitions

8. **Pseudoaddiction** is a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately, the inappropriate behavior ceases.<sup>25</sup>



293. As set forth in more detail below, these statements were false and misleading as evidenced by, *inter alia*, the findings made by the CDC in 2016. Indeed, there is simply no evidence that pseudoaddiction is a real phenomenon. As research compiled by the CDC and others makes clear, pseudoaddiction is pseudoscience—nothing more than a concept Defendants seized upon to help sell more of their actually addicting drugs.

<sup>163</sup> Howard A. Heit, MD, FACP, FASAM and Douglas L. Gourlay, MD, MSc, FRCPC, FASAM, *What a Prescriber Should Know Before Writing the First Prescription, Prescribe Responsibly*, <http://www.prescriberresponsibly.com/articles/before-prescribing-opioids#pseudoaddiction> (last modified July 2, 2015).

1       **5. The Manufacturing Defendants falsely claimed that risk-mitigation  
2 strategies, including tapering and abuse-deterring technologies, made it safe  
3 to prescribe opioids for chronic use.**

4       294. Even when the Manufacturing Defendants acknowledge that opioids pose some  
5 risk of addiction, they dismiss these concerns by claiming that addiction can be easily avoided  
6 and addressed through simple steps. In order to make prescribers feel more comfortable about  
7 starting patients on opioids, the Manufacturing Defendants falsely communicated to doctors that  
8 certain screening tools would allow them to reliably identify patients at higher risk of addiction  
9 and safely prescribe opioids, and that tapering the dose would be sufficient to manage cessation  
of opioid treatment. Both assertions are false.

10      295. For instance, as noted above, Purdue published a REMS for OxyContin in 2010,  
11 in which it described certain steps that needed to be followed for safe opioid use. Purdue stressed  
12 that all patients should be screened for their risk of abuse or addiction, and that such screening  
13 could curb the incidence of addiction.<sup>164</sup>

14      296. The APF also proclaimed in a 2007 booklet, sponsored in part by Purdue, that  
15 “[p]eople with the disease of addiction may abuse their medications, engaging in unacceptable  
16 behaviors like increasing the dose without permission or obtaining the opioid from multiple  
17 sources, among other things. Opioids get into the hands of drug dealers and persons with an  
18 addictive disease as a result of pharmacy theft, forged prescriptions, Internet sales, and even  
19 from other people with pain. It is a problem in our society that needs to be addressed through  
20 many different approaches.”<sup>165</sup>

21      297. On its current website for OxyContin,<sup>166</sup> Purdue acknowledges that certain  
22 patients have higher risk of opioid addiction based on history of substance abuse or mental  
23 illness—a statement which, even if accurate, obscures the significant risk of addiction for all  
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25      <sup>164</sup> *Oxycontin Risk Evaluation and Mitigation Strategy*, *supra* note 153.

26      <sup>165</sup> *Treatment Options: A Guide for People Living with Pain*, *supra* note 137.

27      <sup>166</sup> OxyContin, <https://www.oxycontin.com/index.html> (last visited Mar. 22, 2018).

1 patients, including those without such a history, and comports with statements it has recently  
 2 made that it is “bad apple” patients, and not the opioids, that are arguably the source of the  
 3 opioid crisis:

4  
 5 Assess each patient's risk for opioid addiction,  
 6 abuse, or misuse prior to prescribing  
 7 OxyContin, and monitor all patients receiving  
 8 OxyContin for the development of these  
 9 behaviors and conditions. Risks are increased  
 10 in patients with a personal or family history of  
 11 substance abuse (including drug or alcohol  
 12 abuse or addiction) or mental illness (e.g.,  
 13 major depression). The potential for these risks  
 14 should not, however, prevent the proper  
 management of pain in any given patient.  
 Patients at increased risk may be prescribed  
 opioids such as OxyContin, but use in such  
 patients necessitates intensive counseling  
 about the risks and proper use of OxyContin  
 along with intensive monitoring for signs of  
 addiction, abuse, and misuse.

15 298. Additionally, on its current website, Purdue refers to publicly available tools that  
 16 can assist with prescribing compliance, such as patient-prescriber agreements and risk  
 17 assessments.<sup>167</sup>

18 299. Purdue continues to downplay the severity of addiction and withdrawal and  
 19 claims that dependence can easily be overcome by strategies such as adhering to a tapering  
 20 schedule to successfully stop opioid treatment. On the current website for OxyContin, it instructs  
 21 that “[w]hen discontinuing OxyContin, gradually taper the dosage. Do not abruptly discontinue  
 22 OxyContin.”<sup>168</sup> And on the current OxyContin Medication Guide, Purdue also states that one  
 23 should “taper the dosage gradually.”<sup>169</sup> As a general matter, tapering is a sensible strategy for

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24 <sup>167</sup> ER/LA Opioid Analgesics REMS, Purdue, [http://www.purduepharma.com/healthcare-professionals/responsible-](http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/remis/)  
 25 [use-of-opioids/remis/](http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/remis/) (last visited Mar. 22, 2018).

26 <sup>168</sup> Oxycontin.com, *supra* note 166.

<sup>169</sup> *OxyContin Full Prescribing Information*, Purdue Pharma LP,  
<http://app.purduepharma.com/xmlpublishing/pi.aspx?id=0> (last visited Mar. 22, 2018).

1 cessation of treatment with a variety of medications, such as steroids or antidepressants. But the  
 2 suggestion that tapering is sufficient in the context of chronic use of potent opioids is misleading  
 3 and dangerous, and sets patients up for withdrawal and addiction.

4       300. In its “Dear Healthcare Professional” letter in 2010, Purdue instructed doctors to  
 5 gradually taper someone off OxyContin to prevent signs and symptoms of withdrawal in patients  
 6 who were physically dependent.<sup>170</sup> Nowhere does Purdue warn doctors or patients that tapering  
 7 may be inadequate to safely end opioid treatment and avoid addiction.

8       301. Other Manufacturing Defendants make similar claims. For instance, Endo  
 9 suggests that risk-mitigation strategies enable the safe prescription of opioids. In its currently  
 10 active website, Opana.com, Endo states that assessment tools should be used to assess addiction  
 11 risk, but that “[t]he potential for these risks should not, however, prevent proper management of  
 12 pain in any given patient.”<sup>171</sup>

13       302. On the same website, Endo makes similar statements about tapering, stating  
 14 “[w]hen discontinuing OPANA ER, gradually taper the dosage.”<sup>172</sup>

15       303. Janssen also states on its currently active website, PrescribeResponsibly.com, that  
 16 the risk of opioid addiction “can usually be managed” through tools such as “opioid agreements”  
 17 between patients and doctors.<sup>173</sup>

18       304. Each Manufacturing Defendant’s statements about tapering misleadingly implied  
 19 that gradual tapering would be sufficient to alleviate any risk of withdrawal or addiction while  
 20 taking opioids.

21       305. The Manufacturing Defendants have also made and continue to make false and  
 22 misleading statements about the purported abuse-deterrent properties of their opioid pills to  
 23  
 24

25       <sup>170</sup> *OxyContin Risk Evaluation and Mitigation Strategy*, *supra* note 153.

26       <sup>171</sup> Opana ER, Endo Pharmaceuticals, Inc., <http://www.opana.com> (last visited Mar. 22, 2018).

<sup>172</sup> *Id.*

<sup>173</sup> Heit & Gourlay, *supra* note 163.

1 suggest these reformulated pills are not susceptible to abuse. In so doing, the Manufacturing  
 2 Defendants have increased their profits by selling more pills for substantially higher prices.

3 306. For instance, since at least 2001, Purdue has contended that “abuse resistant  
 4 products can reduce the incidence of abuse.”<sup>174</sup> Its current website touts abuse-deterring  
 5 properties by saying they “can make a difference.”<sup>175</sup>

6 307. On August 17, 2015, Purdue announced the launch of a new website, “Team  
 7 Against Opioid Abuse,” which it said was “designed to help healthcare professionals and  
 8 laypeople alike learn about different abuse-deterring technologies and how they can help in the  
 9 reduction of misuse and abuse of opioids.”<sup>176</sup> This website appears to no longer be active.

10 308. A 2013 study which was authored by at least two doctors who at one time  
 11 worked for Purdue stated that “[a]buse-deterring formulations of opioid analgesics can reduce  
 12 abuse.”<sup>177</sup> In another study from 2016 with at least one Purdue doctor as an author, the authors  
 13 claimed that abuse decreased by as much as 99% in some situations after abuse-deterring  
 14 formulations were introduced.<sup>178</sup>

15 309. Interestingly, one report found that the original safety label for OxyContin, which  
 16 instructed patients not to crush the tablets because it would have a rapid release effect, may have  
 17 inadvertently given opioid users ideas for techniques to get high from these drugs.<sup>179</sup>

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 20 <sup>174</sup> *Oxycontin: Its Use and Abuse*, *supra* note 120.

21 <sup>175</sup> *Opioids with Abuse-Deterrent Properties*, Purdue, [http://www.purduepharma.com/healthcare-](http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/)  
[professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/](http://www.purduepharma.com/healthcare-professionals/responsible-use-of-opioids/opioids-with-abuse-deterrent-properties/) (last visited Mar. 22, 2018).

22 <sup>176</sup> *Purdue Pharma L.P. Launches TeamAgainstOpioidAbuse.com*, Purdue (Aug. 17, 2015),  
<http://www.purduepharma.com/news-media/2015/08/purdue-pharma-l-p-launches-teamagainstopioidabuse-com/>.

23 <sup>177</sup> Paul M. Coplan, Hrishikesh Kale, Lauren Sandstrom, Craig Landau, and Howard D. Chilcoat, *Changes in*  
*oxycodone and heroin exposures in the National Poison Data System after introduction of extended-release*  
*oxycodone with abuse-deterring characteristics*, 22 (12) *Parmaepidemiol Drug Saf.* 1274-82 (Sept. 30, 2013),  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4283730/>.

24 <sup>178</sup> Paul M. Coplan, Howard D. Chilcoat, Stephen Butler, Edward M. Sellers, Aditi Kadakia, Venkatesh  
 Harikrishnan, J. David Haddox, and Richard C. Dart, *The effect of an abuse-deterring opioid formulation*  
*(OxyContin) on opioid abuse-related outcomes in the postmarketing setting*, 100 *Clin. Pharmacol. Ther.* 275-86  
 (June 22, 2016), <http://onlinelibrary.wiley.com/doi/10.1002/cpt.390/full>.

25 <sup>179</sup> *OxyContin Abuse and Diversion and Efforts to Address the Problem*, *supra* note 32.

1       310. In 2012, Defendant Endo replaced the formula for Opana ER with a new formula  
 2 with abuse-deterrent properties that it claimed would make Opana ER resistant to manipulation  
 3 from users to snort or inject it. But the following year, the FDA concluded:

4           While there is an increased ability of the reformulated version of Opana ER to resist  
 5 crushing relative to the original formulation, study data show that the reformulated  
 6 version's extended-release features can be compromised when subjected to other  
 forms of manipulation, such as cutting, grinding, or chewing, followed by  
 swallowing.

7           Reformulated Opana ER can be readily prepared for injection, despite Endo's claim  
 8 that these tablets have "resistance to aqueous extraction (i.e., poor syringeability)." It also appears that reformulated Opana ER can be prepared for snorting using  
 9 commonly available tools and methods.

10          The postmarketing investigations are inconclusive, and even if one were to treat  
 11 available data as a reliable indicator of abuse rates, one of these investigations also  
 12 suggests the troubling possibility that a higher percentage of reformulated Opana  
 ER abuse is via injection than was the case with the original formulation.<sup>180</sup>

13       311. Despite the FDA's determination that the evidence did not support Endo's claims  
 14 of abuse-deterrence, Endo advertised its reformulated pills as "crush resistant" and directed its  
 15 sales representatives to represent the same to doctors. Endo improperly marketed Opana ER as  
 16 crush-resistant, when Endo's own studies showed that the pill could be crushed and ground. In  
 17 2016, Endo reached an agreement with the Attorney General of the State of New York that  
 18 required Endo to discontinue making such statements.<sup>181</sup>

19       312. The Manufacturing Defendants' assertions that their reformulated pills could curb  
 20 abuse were false and misleading, as the CDC's 2016 Guideline, discussed below, confirm.

21       313. Ultimately, even if a physician prescribes opioids after screening for abuse risk,  
 22 advising a patient to taper, and selecting brand-name, abuse-deterrent formulations, chronic

23  
 24 <sup>180</sup> *FDA Statement: Original Opana ER Relisting Determination*, U.S. Food & Drug Admin. (May 10, 2013),  
<https://wayback.archive-it.org/7993/20171102214123/https://www.fda.gov/Drugs/DrugSafety/ucm351357.htm>.

25       26 <sup>181</sup> Press Release, Attorney General Eric T. Schneiderman, *A.G. Schneiderman Announces Settlement with Endo Health Solutions Inc. & Endo Pharmaceuticals Inc. Over Marketing of Prescription Opioid Drugs* (Mar. 3, 2016),  
<https://ag.ny.gov/press-release/ag-schneiderman-announces-settlement-endo-health-solutions-inc-endo-pharmaceuticals>.

1 opioid use still comes with significant risks of addiction and abuse. The Manufacturing  
 2 Defendants' statements to the contrary were designed to create a false sense of security and  
 3 assure physicians that they could safely prescribe potent narcotics to their patients.

4 **E. Research by Washington State's Department of Labor and Industries Highlights the  
 5 Falseness of the Manufacturing Defendants' Claims.**

6 314. Contrary to the Manufacturing Defendants' misrepresentations about the benefits  
 7 and risks of opioids, growing evidence suggests that using opioids to treat chronic pain leads to  
 8 overall negative outcomes, delaying or preventing recovery and providing little actual relief, all  
 9 while presenting serious risks of overdose.

10 315. One place where this evidence surfaced is the Washington State Department of  
 11 Labor and Industries ("L&I"). The Department of L&I runs the state's workers' compensation  
 12 program, which covers all employees in the state, other than those who work for large companies  
 13 and government entities. In 2000, L&I's new chief pharmacist, Jaymie Mai, noticed an increase  
 14 in prescription of opioids for chronic pain, approximately 50 to 100 cases a month.<sup>182</sup> As she  
 15 took a closer look at the prescription data, she discovered some of these same workers were  
 16 dying from opioid overdoses. That workers suffered back pain or sprained knees on the job was  
 17 nothing new, but workers dying from their pain medication was assuredly not business as usual.  
 18 Mai reported what she was seeing to L&I's Medical Director, Dr. Gary Franklin.<sup>183</sup>

19 316. In addition to being L&I's Medical Director, Dr. Franklin is a research professor  
 20 at the University of Washington in the departments of Environmental Health, Neurology, and  
 21 Health Services. Dr. Franklin and Mai undertook a thorough analysis of all recorded deaths in  
 22 the state's workers' comp system. In 2005, they published their findings in the American Journal  
 23 of Industrial Medicine.<sup>184</sup>

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24 <sup>182</sup> Quinones, *supra* note 45, at 203.  
 25 <sup>183</sup> *Id.*  
 26 <sup>184</sup> Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith A. Turner, Ph.D., Deborah Fulton-Kehoe, Ph.D., MPH, and Linda Grant, BSN, MBA, *Opioid dosing trends and mortality in Washington State Workers' Compensation, 1996-2002*, 48 Am J Ind Med 91-99 (2005).

1       317. Their research showed that the total number of opioid prescriptions paid for by  
 2 the Workers' Compensation Program tripled between 1996 and 2006.<sup>185</sup> Not only did the number  
 3 of prescriptions balloon, so too did the doses; from 1996 to 2002 the mean daily morphine  
 4 equivalent dose ("MED") nearly doubled, and remained that way through 2006.<sup>186</sup> As injured  
 5 Washington workers were given more prescriptions of higher doses of opioids, the rates of  
 6 opioid overdoses among that population jumped, from zero in 1996 to more than twenty in 2005.  
 7 And in 2009, over thirty people receiving opioid prescriptions through the Workers'  
 8 Compensation Program died of an opioid overdose.<sup>187</sup>

9       318. Armed with these alarming statistics, Dr. Franklin, in conjunction with other  
 10 doctors in Washington, set out to limit the doses of opioids prescribed through the workers'  
 11 compensation program. As part of that effort, in 2007 the Agency Medical Directors Group  
 12 launched an Interagency Guideline on Opioid Dosing, aimed at reducing the numbers of opioid  
 13 overdoses. Through this, and other related efforts, both the rates of opioid prescriptions and the  
 14 sizes of doses have declined in Washington, beginning in 2009. As opioid prescriptions rates for  
 15 injured workers have declined, so too has the death rate among this population.<sup>188</sup>

16       319. Moreover, additional research from L& I showed that the use of opioids to treat  
 17 pain after an injury actually prevents or slows a patient's recovery.

18       320. In a study of employees who had suffered a low back injury on the job, Dr.  
 19 Franklin showed that if an injured worker was prescribed opioids soon after the injury, high  
 20 doses of opioids, or opioids for more than a week, the employee was far more likely to  
 21 experience negative health outcomes than the same employee who was not prescribed opioids in  
 22 these manners.

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23       <sup>185</sup> Gary M. Franklin, M.D., MPH, Jaymie Mai, Pharm.D., Thomas Wickizer, Ph.D., Judith Turner, Ph.D., Mark  
 24 Sullivan, M.D., Ph.D., Thomas Wickizer, Ph.D., and Deborah Fulton-Kehoe, Ph.D., *Bending the Prescription*  
 25 *Opioid Dosing and Mortality Curves: Impact of the Washington State Opioid Dosing Guideline*, 55 Am J Ind Med  
 325, 327 (2012).

26       <sup>186</sup> *Id.* at 327-28.

187 *Id.* at 328.

188 *Id.*

1       321. Specifically, the study showed that, after adjusting for the baseline covariates,  
 2 injured workers who received a prescription opioid for more than seven days during the first six  
 3 weeks after the injury were 2.2 times more likely to remain disabled a year later than workers  
 4 with similar injuries who received no opioids at all. Similarly, those who received two  
 5 prescriptions of opioids for the injury were 1.8 times more likely to remain disabled a year after  
 6 their injury than workers who received no opioids at all, and those receiving daily doses higher  
 7 than 150 MED were over twice as likely to be on disability a year later, relative to workers who  
 8 received no opioids.<sup>189</sup>

9       322. In sum, not only do prescription opioids present significant risks of addiction and  
 10 overdose, but they also hinder patient recovery after an injury.

11       323. This dynamic presents problems for employers, too, who bear significant costs  
 12 when their employees do not recover quickly from workplace injuries. Employers are left  
 13 without their labor force and may be responsible for paying for the injured employee's disability  
 14 for long periods of time.

15       **F. The 2016 CDC Guideline and Other Recent Studies Confirm That the  
 16 Manufacturing Defendants' Statements About the Risks and Benefits of Opioids  
 17 Are Patently False.**

18       324. Contrary to the statements made by the Manufacturing Defendants in their well-  
 19 orchestrated campaign to tout the benefits of opioids and downplay their risks, recent studies  
 20 confirm the Manufacturing Defendants' statements were false and misleading.

21       325. The CDC issued its *Guideline for Prescribing Opioids for Chronic Pain* on March  
 22 15, 2016.<sup>190</sup> The 2016 CDC Guideline, approved by the FDA, "provides recommendations for  
 23 primary care clinicians who are prescribing opioids for chronic pain outside of active cancer

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 25       <sup>189</sup> Franklin, GM, Stover, BD, Turner, JA, Fulton-Kehoe, D, Wickizer, TM, *Early opioid prescription and  
 subsequent disability among workers with back injuries: the Disability Risk Identification Study Cohort*, 33 Spine  
 199, 201-202.

26       <sup>190</sup> 2016 CDC Guideline, *supra* note 33.

1 treatment, palliative care, and end-of-life care.” The Guideline also assesses the risks and harms  
 2 associated with opioid use.

3 326. The 2016 CDC Guideline is the result of a thorough and extensive process by the  
 4 CDC. The CDC issued the Guideline after it “obtained input from experts, stakeholders, the  
 5 public, peer reviewers, and a federally chartered advisory committee.” The recommendations in  
 6 the 2016 CDC Guideline were further made “on the basis of a systematic review of the best  
 7 available evidence . . .”

8 327. The CDC went through an extensive and detailed process to solicit expert  
 9 opinions for the Guideline:

10 CDC sought the input of experts to assist in reviewing the evidence and providing  
 11 perspective on how CDC used the evidence to develop the draft recommendations.  
 12 These experts, referred to as the “Core Expert Group” (CEG) included subject  
 13 matter experts, representatives of primary care professional societies and state  
 14 agencies, and an expert in guideline development methodology. CDC identified  
 15 subject matter experts with high scientific standing; appropriate academic and  
 16 clinical training and relevant clinical experience; and proven scientific excellence  
 17 in opioid prescribing, substance use disorder treatment, and pain management.  
 18 CDC identified representatives from leading primary care professional  
 19 organizations to represent the audience for this guideline. Finally, CDC identified  
 20 state agency officials and representatives based on their experience with state  
 21 guidelines for opioid prescribing that were developed with multiple agency  
 22 stakeholders and informed by scientific literature and existing evidence-based  
 23 guidelines.

24 328. The 2016 Guideline was also peer-reviewed pursuant to “the final information  
 25 quality bulletin for peer review.” Specifically, the Guideline describes the following independent  
 26 peer-review process:

27 [P]eer review requirements applied to this guideline because it provides influential  
 28 scientific information that could have a clear and substantial impact on public- and  
 29 private-sector decisions. Three experts independently reviewed the guideline to  
 30 determine the reasonableness and strength of recommendations; the clarity with  
 31 which scientific uncertainties were clearly identified; and the rationale, importance,  
 32 clarity, and ease of implementation of the recommendations. CDC selected peer  
 33 reviewers based on expertise, diversity of scientific viewpoints, and independence  
 34 from the guideline development process. CDC assessed and managed potential  
 35 conflicts of interest using a process similar to the one as described for solicitation  
 36 of expert opinion. No financial interests were identified in the disclosure and review

1 process, and nonfinancial activities were determined to be of minimal risk; thus, no  
 2 significant conflict of interest concerns were identified.

3 329. The findings in the 2016 CDC Guideline both confirmed the existing body of  
 4 scientific evidence regarding the questionable efficacy of opioid use and contradicted  
 5 Defendants' statements about opioids.

6 330. For instance, the Guideline states “[e]xtensive evidence shows the possible harms  
 7 of opioids (including opioid use disorder, overdose, and motor vehicle injury)” and that “[o]pioid  
 8 pain medication use presents serious risks, including overdose and opioid use disorder.” The  
 9 Guideline further confirms there are significant symptoms related to opioid withdrawal,  
 10 including drug cravings, anxiety, insomnia, abdominal pain, vomiting, diarrhea, sweating,  
 11 tremor, tachycardia (rapid heartbeat), spontaneous abortion and premature labor in pregnant  
 12 women, and the unmasking of anxiety, depression, and addiction. These findings contradict  
 13 statements made by Defendants regarding the minimal risks associated with opioid use,  
 14 including that the risk of addiction from chronic opioid use is low.

15 331. The Guideline also concludes that there is “[n]o evidence” to show “a long-term  
 16 benefit of opioids in pain and function versus no opioids for chronic pain . . .” Furthermore, the  
 17 Guideline indicates that “continuing opioid therapy for 3 months substantially increases the risk  
 18 of opioid use disorder.” Indeed, the Guideline indicates that “[p]atients who do not experience  
 19 clinically meaningful pain relief early in treatment . . . are unlikely to experience pain relief with  
 20 longer-term use,” and that physicians should “reassess[] pain and function within 1 month” in  
 21 order to decide whether to “minimize risks of long-term opioid use by discontinuing opioids”  
 22 because the patient is “not receiving a clear benefit.” These findings flatly contradict claims  
 23 made by the Defendants that there are minimal or no adverse impacts of long-term opioid use, or  
 24 that long-term opioid use could actually improve or restore a patient’s function.

25 332. In support of these statements about the lack of long-term benefits of opioid use,  
 26 the CDC concluded that “[a]lthough opioids can reduce pain during short-term use, the clinical

1 evidence review found insufficient evidence to determine whether pain relief is sustained and  
 2 whether function or quality of life improves with long-term opioid therapy.” The CDC further  
 3 found that “evidence is limited or insufficient for improved pain or function with long-term use  
 4 of opioids for several chronic pain conditions for which opioids are commonly prescribed, such  
 5 as low back pain, headache, and fibromyalgia.”

6       333. With respect to opioid dosing, the Guideline reports that “[b]enefits of high-dose  
 7 opioids for chronic pain are not established” while the “risks for serious harms related to opioid  
 8 therapy increase at higher opioid dosage.” The CDC specifically explains that “there is now an  
 9 established body of scientific evidence showing that overdose risk is increased at higher opioid  
 10 dosages.” The CDC also states that there is an “increased risk[] for opioid use disorder,  
 11 respiratory depression, and death at higher dosages.” As a result, the CDC advises doctors to  
 12 “avoid increasing dosage” above 90 MME per day. These findings contradict statements made  
 13 by Defendants that increasing dosage is safe and that under-treatment is the cause for certain  
 14 patients’ aberrant behavior.

15       334. The 2016 CDC Guideline also contradicts statements made by Defendants that  
 16 there are reliable risk-mitigation tactics to reduce the risk of addiction. For instance, the  
 17 Guideline indicates that available risk screening tools “show insufficient accuracy for  
 18 classification of patients as at low or high risk for [opioid] abuse or misuse” and counsels that  
 19 doctors “should not overestimate the ability of these tools to rule out risks from long-term opioid  
 20 therapy.”

21       335. Finally, the 2016 CDC Guideline states that “[n]o studies” support the notion that  
 22 “abuse-deterrant technologies [are] a risk mitigation strategy for deterring or preventing abuse,”  
 23 noting that the technologies—even when they work—“do not prevent opioid abuse through oral  
 24 intake, the most common route of opioid abuse, and can still be abused by nonoral routes.” In  
 25 particular, the CDC found as follows:

26       The “abuse-deterrant” label does not indicate that there is no risk for abuse. No  
 studies were found in the clinical evidence review assessing the effectiveness of

1 abuse-deterrant technologies as a risk mitigation strategy for deterring or  
 2 preventing abuse. In addition, abuse-deterrant technologies do not prevent  
 3 unintentional overdose through oral intake. Experts agreed that recommendations  
 could not be offered at this time related to use of abuse-deterrant formulations.

4 Accordingly, the CDC's findings regarding "abuse-deterrant technologies" directly contradict  
 5 Purdue and Endo's claims that their new pills deter or prevent abuse.

6       336. Notably, in addition to the findings made by the CDC in 2016, the Washington  
 7 State Agency Medical Directors' Group (AMDG)—a collaboration among several Washington  
 8 State Agencies—published its *Interagency Guideline on Prescribing Opioids for Pain* in 2015.  
 9 The AMDG came to many of the same conclusions as the CDC did. For example, the AMDG  
 10 found that "there is little evidence to support long term efficacy of [chronic opioid analgesic  
 11 therapy, or "COAT"] in improving function and pain, [but] there is ample evidence of its risk for  
 12 harm . . ."<sup>191</sup>

13       337. In addition, as discussed above, in contrast to Defendants' statements that the  
 14 1980 Porter and Jick letter provided evidence of the low risk of opioid addiction in pain patients,  
 15 the NEJM recently published a letter largely debunking the use of the Porter and Jick letter as  
 16 evidence for such a claim.<sup>192</sup> The researchers demonstrated how the Porter and Jick letter was  
 17 irresponsibly cited and, in some cases, "grossly misrepresented," when in fact it did not provide  
 18 evidence supporting the broad claim of low addiction risk for all patients prescribed opioids for  
 19 pain. As noted above, Dr. Jick reviewed only files of patients administered opioids in a hospital  
 20 setting, rather than patients sent home with a prescription for opioids to treat chronic pain.

21       338. The authors of the 2017 letter described their methodology as follows:

22       We performed a bibliometric analysis of this [1980] correspondence from its  
 23 publication until March 30, 2017. For each citation, two reviewers independently  
 24 evaluated the portrayal of the article's conclusions, using an adaptation of an  
 established taxonomy of citation behavior along with other aspects of

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25       <sup>191</sup> *Interagency Guideline on Prescribing Opioids for Pain*, Agency Med. Directors' Group (June 2015),  
 26 <http://www.agencymeddirectors.wa.gov/Files/2015AMDGOpoidGuideline.pdf>.

192 Leung, et al., *supra* note 110.

1 generalizability . . . For context, we also ascertained the number of citations of  
 2 other stand-alone letters that were published in nine contemporaneous issues of the  
 3 *Journal* (in the index issue and in the four issues that preceded and followed it).

4 We identified 608 citations of the index publication and noted a sizable increase  
 5 after the introduction of OxyContin (a long-acting formulation of oxycodone) in  
 6 1995 . . . **Of the articles that included a reference to the 1980 letter, the authors**  
 7 **of 439 (72.2%) cited it as evidence that addiction was rare in patients treated**  
 8 **with opioids. Of the 608 articles, the authors of 491 articles (80.8%) did not**  
 9 **note that the patients who were described in the letter were hospitalized at the**  
**time they received the prescription, whereas some authors grossly**  
**misrepresented the conclusions of the letter . . .** Of note, affirmational citations  
 have become much less common in recent years. In contrast to the 1980  
 correspondence, 11 stand-alone letters that were published contemporaneously by  
 the Journal were cited a median of 11 times.<sup>193</sup> (Emphasis added).

10 339. The researchers provided examples of quotes from articles citing the 1980 letter,  
 11 and noted several shortcomings and inaccuracies with the quotations. For instance, the  
 12 researchers concluded that these quotations (i) “overstate[] conclusions of the index publication,”  
 13 (ii) do[] not accurately specify its study population,” and (iii) did not adequately address  
 14 “[l]imitations to generalizability.”<sup>194</sup>

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 193 *Id.* (emphasis added).

25 194 Supplementary Appendix to Pamela T.M. Leung, B.Sc. Pharm., Erin M. Macdonald, M.Sc., Matthew B.  
 26 Stanbrook, M.D., Ph.D., Irfan Al Dhalla, M.D., David N. Juurlink, M.D., Ph.D., *A 1980 Letter on the Risk of*  
*Opioid Addiction*, 376 N Engl J Med 2194-95 (June 1, 2017),  
[http://www.nejm.org/doi/suppl/10.1056/NEJMc1700150/suppl\\_file/nejmc1700150\\_appendix.pdf](http://www.nejm.org/doi/suppl/10.1056/NEJMc1700150/suppl_file/nejmc1700150_appendix.pdf).

Quote	Reference	Comment
"This pain population with no abuse history is literally at no risk for addiction."	Kowal N. What is the issue?: pseudoaddiction or undertreatment of pain. <i>Nurs Econ</i> 1998;17(6):346-9	
"In truth, however, the medical evidence overwhelmingly indicates that properly administered opioid therapy rarely if ever results in "accidental addiction" or "opioid abuse"."	Libby RT. Treating Doctors as Drug Dealers: The Drug Enforcement Administration's War on Prescription Painkillers. <i>The Independent Review</i> 2006;10(4):511-545.	
"Fear of addiction may lead to reluctance by the physician to prescribe. [...] However, there is no evidence that this occurs when prescribing opioids for pain."	Iles S, Catterall JR, Hanks G. Use of opioid analgesics in a patient with chronic abdominal pain. <i>Int J Clin Pract</i> 2002;56(3):227-8.	
"In reality, medical opioid addiction is very rare. In Porter and Jick's study on patients treated with narcotics, only four of the 11,882 cases showed psychological dependency."	Liu W, Xie S, Yue L, et al. Investigation and analysis of oncologists' knowledge of morphine usage in cancer pain treatment. <i>Onco Targets Ther</i> 2014;7:729-37.	Overstates conclusions of the index publication does not accurately specify its study population. Limitations to generalizability are not otherwise explicitly mentioned.
"Physicians are frequently concerned about the potential for addiction when prescribing opiates; however, there have been studies suggesting that addiction rarely evolves in the setting of painful conditions."	Curtis LA, Morrell TD, Todd KH. Pain Management in the Emergency Department 2006;8(7).	
"Although medicine generally regards anecdotal information with disdain (rigorously controlled double-blind clinical trials are the "gold standard"), solid data on the low risk of addiction to opioid analgesics and the manageability of adverse side effects have been ignored or discounted in favor of the anecdotal, the scientifically unsupported, and the clearly fallacious."	Rich BA. Prioritizing pain management in patient care. Has the time come for a new approach. <i>Postgrad Med</i> 2001;110(3):15-7.	
"The Boston Drug Surveillance Program reviewed the charts of nearly 12,000 cancer pain patients treated over a decade and found only four of them could be labeled as addicts."	Levy MH. Pharmacologic management of cancer pain. <i>Semin Oncol</i> 1994;21(6):718-39.	Incorrectly identifies the index study population as cancer patients; does not otherwise address limitations to generalizability.

340. Based on this review, the researchers concluded as follows:

[W]e found that a five-sentence letter published in the Journal in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers' concerns about the risk of addiction associated with long-term opioid therapy. In 2007, the manufacturer of OxyContin and three senior executives pleaded guilty to federal criminal charges that they misled regulators, doctors, and patients about the risk of addiction associated with the drug. Our findings highlight the potential consequences of inaccurate citation and underscore the need for diligence when citing previously published studies.<sup>195</sup>

195 Leung, et al., *supra* note 110.

1       341. These researchers' careful analysis demonstrates the falsity of Defendants' claim  
 2 that this 1980 letter was evidence of a low risk of addiction in opioid-treated patients. By casting  
 3 this letter as evidence of low risk of addiction, Defendants played fast and loose with the truth,  
 4 with blatant disregard for the consequences of their misrepresentations.

5       **G. Clallam County Has Been Directly Affected by the Opioid Epidemic Caused by**  
 6 **Defendants.**

7       342. Clallam County, which occupies the northern portion of the Olympic Peninsula in  
 8 northwestern Washington State, has approximately 74,000 residents.<sup>196</sup> Clallam County pays  
 9 health insurance costs for its employees and their families, including for their opioid  
 10 prescriptions and opioid-related healthcare costs.

11       343. Clallam County has been particularly hard hit by the consequences of the opioid  
 12 epidemic. According to the Washington State Department of Health, the rate of opioid-related  
 13 overdose deaths in Clallam County from 2012 to 2016 was the highest in the state, at 16.5 deaths  
 14 per 100,000 in the general population.<sup>197</sup>

15       344. Inpatient hospitalizations for opioid overdoses in Clallam County have also  
 16 increased significantly, from 107 such hospitalizations in 2010, to 260 in 2015—a 142%  
 17 increase.<sup>198</sup>

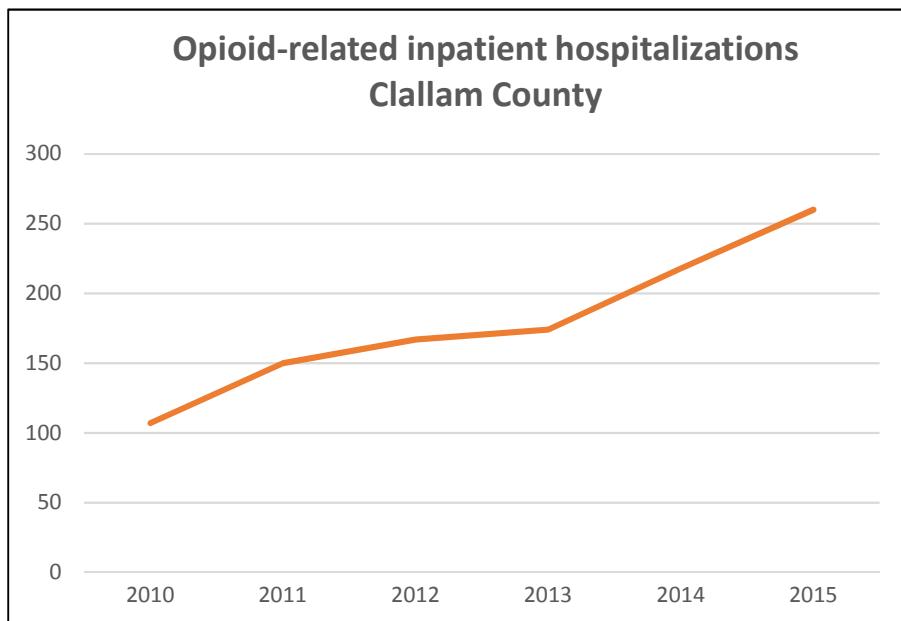
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<sup>196</sup> April 1, 2017 Population of Cities, Towns and Counties Used for Allocation of Selected State Revenues - State of  
 25 Washington, [https://www.ofm.wa.gov/sites/default/files/public/legacy/pop/april1/ofm\\_april1\\_population\\_final.pdf](https://www.ofm.wa.gov/sites/default/files/public/legacy/pop/april1/ofm_april1_population_final.pdf)  
 (last visited Mar. 22, 2018).

26       <sup>197</sup> *Opioid-related Deaths in Washington State*, *supra* note 6.

26       <sup>198</sup> *Clallam County Opioid Surveillance Dashboard*, Clallam County Health & Human Servs. (Aug. 2017),  
<https://websrv7.clallam.net/forms/uploads/CCHHSOpioidSurveillanceReport.pdf>.



345. Clallam County has seen a corresponding rise in the number of people entering treatment for opioid use. Between 2002-2004 and 2011-2013, publicly funded treatment admissions in Clallam County involving any opioid grew by 468.5%.<sup>199</sup> While these figures include heroin as well as prescription opioids, survey data from Clallam County indicates that the overwhelming majority of heroin users started with prescription opioids: 70% of Clallam County respondents to the 2015 Drug Injector Survey stated that they became hooked on prescription opioids before using heroin.<sup>200</sup>

346. The crisis will have long-lasting consequences, in part because it disproportionately affects young people in the County. One third of all opioid overdoses reported in Clallam County involve individuals between 18 and 29 years old. Many of those who develop opioid-use disorder in their twenties will require treatment for years or decades to come.

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<sup>199</sup> *Opioid Trends Across Washington State*, U. of Wash. Alcohol & Drug Abuse Inst. (Apr. 2015), <http://adai.uw.edu/pubs/infobriefs/ADAI-IB-2015-01.pdf>.

<sup>200</sup> Olympic Community of Health Report; and Susan Kingston & Caleb Banta-Green, *Results from the 2015 Washington State Drug Injector Health Survey*, U. of Wash. Alcohol & Drug Abuse Inst. (Feb. 2016), <http://adai.uw.edu/pubs/infobriefs/2015druginjectorhealthsurvey.pdf>.

1       347. The opioid epidemic also affects children whose parents are struggling with  
 2 opioid-use disorder. One indicator of this in Clallam County is the significant rise in dependency  
 3 court proceedings, which are initiated by the State in situations of abuse, neglect, or  
 4 abandonment and where there is no parent able to safely care for the child. Although dependency  
 5 filings have become more common, they represent a fairly drastic measure taken as a last resort:  
 6 asking the court to intervene to protect the child from harm and allow the State to temporarily  
 7 assume legal custody of the child. Between 2008 and 2013, the number of dependency filings in  
 8 Clallam County doubled, from 74 to 151. This increase has been driven, in significant part, by  
 9 the opioid epidemic, as a result of children being removed from homes where opioids are being  
 10 abused.

11       348. Clallam County has been a leader in confronting the emergency caused by  
 12 Defendants' reckless promotion and distribution of prescription opioids. The County's public  
 13 health administrators were among the first to recognize the profound impacts opioids were  
 14 having on the community, and they and the County have taken groundbreaking actions to  
 15 address the fallout from this crisis.

16       349. In January 2016, Clallam County became the first county in Washington to  
 17 mandate reporting of non-fatal as well as fatal overdoses. Such overdose reporting allows the  
 18 County to offer timely direct services such as naloxone, counseling, and medication-assisted  
 19 treatment ("MAT") referrals, in addition to allowing improved surveillance when a common  
 20 source of overdose (such as a bad batch or a higher potency opioid like fentanyl) is suspected. In  
 21 February 2016, the Clallam County jail implemented the first MAT program for opioid-addicted  
 22 inmates inside a jail on the West Coast. In September 2016, Clallam County worked with  
 23 neighboring Jefferson and Kitsap Counties as part of a project known as Olympic Community of  
 24 Health to initiate the Three-County Coordinated Opioid Response Project (3CCORP), a multi-  
 25 sector collaborative effort to address the opioid epidemic in the region. Clallam County Public  
 26

1 Health, Clallam County Jail, and Clallam County Health and Human Services are all part of  
 2 3CCORP and are providing extensive staff time to support 3CCORP's efforts.

3 350. Within 3CCORP, members have formed three workgroups to address (1)  
 4 Overdose Prevention, (2) Treatment, and (3) Prevention. The Overdose Prevention Workgroup's  
 5 work includes, for example, identifying baseline metrics for overdose response and finding ways  
 6 to increase training and the availability of naloxone. The Prevention Workgroup is working on  
 7 reforming prescribing practices through the 6 Building Blocks to Safer Opioid Prescribing  
 8 model,<sup>201</sup> developed by researchers at the University of Washington and Group Health (now  
 9 Kaiser) Research Institute in Seattle, and is aimed at revising chronic opioid therapy practices in  
 10 primary care clinics.<sup>202</sup>

11 351. The Treatment Workgroup collaborated and successfully obtained Washington  
 12 State Department of Social and Health Services funding to support a "hub and spoke" model of  
 13 treatment for opioid-use disorder. Now being adapted and implemented in various regions after  
 14 its success in Vermont,<sup>203</sup> the "hub and spoke" model provides specialized substance-use  
 15 disorder treatment in a "hub" with care managers in several "spokes." In Washington State's  
 16 adaptation of the model, the hub must be a primary care clinic, a community-based health center,  
 17 or an opioid treatment program, capable of providing on site at least two of the three FDA-  
 18 approved medications for opioid-use disorder (methadone, buprenorphine, and naltrexone), with  
 19 a minimum of two waivered providers, a nurse care manager, and a care coordinator. A  
 20 minimum of five spokes must each have a care coordinator and offer supportive recovery  
 21 services such as counseling, but can include locations such as syringe exchange programs or

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22  
 23<sup>201</sup> Six Building Blocks, <https://www.improvingopioidcare.org/> (last visited Apr. 17, 2018).

24<sup>202</sup> Michael L. Parchman, MD, MPH, Michael Von Korff, PhD, Laura-Mae Baldwin, MD, Mark Stephens, BS,  
 Brooke Ike, MPH, DeAnn Cromp, MPH, Clariss Hsu, PhD, and Ed H. Wagner, MD, MPH, *Primary Care Clinic  
 Re-Design for Prescription Opioid Management*, 30(1) JABFM 44-51 (Jan.-Feb. 2017),  
[https://www.improvingopioidcare.org/wp-content/uploads/2018/02/JABFM-article\\_2017.pdf](https://www.improvingopioidcare.org/wp-content/uploads/2018/02/JABFM-article_2017.pdf).

25<sup>203</sup> John R. Brooklyn, MD and Stacey C. Sigmon, PhD, *Vermont Hub-and-Spoke Model of Care For Opioid Use  
 Disorder: Development, Implementation, and Impact*, 11(4) J Addict Med 286-292 (July-Aug. 2017),  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5537005/>.

1 correctional facilities, as the goal of the spokes is offer low barriers for accessing treatment.  
 2 While the 3CCORP Treatment Workgroup recognized that ideally each of the three counties  
 3 would have a hub, currently available resources limit the model to one hub for the three counties.  
 4 Peninsula Community Health Services in Kitsap County was selected as the “hub,” and the  
 5 spokes include the North Olympic Healthcare Network in Port Angeles in Clallam County. As of  
 6 March 2018, the project had already surpassed its treatment induction goal with 260 treatment  
 7 inductions.

8       352. In addition, Clallam County will soon have an outpatient opioid treatment facility.  
 9 Salish Behavioral Health Organization, which oversees Medicaid services in Kitsap, Clallam and  
 10 Jefferson counties, contracted with BayMark Health Services to create opioid treatment centers  
 11 in both Kitsap and Clallam counties.

12       353. Nevertheless, the County continues to suffer the consequences of Defendants’  
 13 aggressive marketing scheme and excessive distribution of prescription opioids. These  
 14 consequences will continue well into the future. Each day that Defendants continue to evade  
 15 responsibility for the epidemic they caused, the County must continue to allocate substantial  
 16 resources to address it. And, to truly end the crisis in Clallam County will require resources the  
 17 County does not have. The costs described in the following sections are illustrative but not  
 18 exhaustive examples of the significant burden the opioid crisis has imposed on the County.

19       **1. Clallam County Health and Human Services has incurred enormous costs in  
 20 dealing with the crisis caused by Defendants.**

21       354. Clallam County Health and Human Services (HHS) is responsible for delivery of  
 22 services to some of the most vulnerable citizens in Clallam County. HHS serves a mainly rural  
 23 population and has limited capacity and funding to address the long-term challenges created by  
 24 the opioid crisis. Notwithstanding its limited resources, HHS has been battling the opioid  
 25 epidemic in Clallam on multiple fronts. The Human Services division, for example, oversees and  
 26 supports nonprofit agencies that provide drug treatment and substance abuse prevention. The

1 work of the Public Health division includes opioid overdose reporting, review, and follow-up,  
 2 running a syringe exchange program, naloxone training and distribution, and coordination with  
 3 chemical dependency professionals and MAT providers.

4       355. As discussed above, HHS has been a leader in the regional opioid response  
 5 through 3CCORP. HHS staff also participate in numerous other programs and regional activities,  
 6 working in collaboration with other health jurisdictions, local tribal nations, the chemical  
 7 dependency treatment community, and law enforcement to address the opioid crisis. To promote  
 8 awareness and community education, Public Health staff regularly give presentations regarding  
 9 opioid use and addiction and publish articles on addiction.

10       356. In addition to supporting the implementation of the regional hub and spoke  
 11 network and advocating for the stand-alone outpatient opioid treatment program in Clallam as  
 12 discussed above, HHS has been advocating at the local, state, and federal level to expand  
 13 existing MAT services to meet the community need, by increasing the number of waivered  
 14 providers and expanding a nurse-managed MAT program at the County's federally qualified  
 15 community health center, North Olympic Healthcare Network.

16       357. HHS also operates the County's Syringe Services Program (SSP). Not only does  
 17 SSP provide access to sterile syringes to prevent the transmission of blood-borne diseases such  
 18 as HIV and hepatitis C, it has become a center for the delivery of key services to address the  
 19 opioid crisis. For example, SSP provides MAT referral services, naloxone distribution, case  
 20 management services and chemical dependency counseling, HIV and hepatitis C testing,  
 21 immunizations, and syringe disposal education.<sup>204</sup> Over the past decade the number of clients  
 22 engaging SSP's services as well as the number of syringes exchanged have increased. SSP

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 26<sup>204</sup> *Syringe Services*, Clallam County, Washington, <http://www.clallam.net/hhs/PublicHealth/syringeservices.html>  
 (last visited Apr. 17, 2017).

1 exchange 234,270 needles in 2016,<sup>205</sup> compared to 77,529 clean syringes distributed in 2009.<sup>206</sup>  
 2 In late 2017, the Clallam County Board of Health directed HHS to prepare to expand SSP to  
 3 Forks, on the western edge of the County.<sup>207</sup>

4       358. Clallam County HHS has devoted significant resources to combatting the opioid  
 5 epidemic and will continue to do so into the foreseeable future. Ultimately, however, the  
 6 resources the County has dedicated to combatting the opioid epidemic result in a loss of capacity  
 7 to address other important public health programs, such as communicable disease investigations,  
 8 immunizations, and well-child screening.

9           **2. The County's justice system—both criminal and civil—has incurred  
 10 substantial costs in responding to the epidemic caused by Defendants.**

11       359. The opioid epidemic has imposed serious costs and burdens on the County's  
 12 criminal justice resources. The County has had more opioid-related crimes to investigate and  
 13 prosecute, and the County jail now houses more people arrested or convicted for drug-related  
 14 crimes. But the costs aren't limited to the criminal justice system; on the civil side, the County  
 15 has experienced a rise in the need for child-welfare interventions, including dependency  
 16 proceedings and related services. While these actions are critical to keeping people safe in the  
 17 County, the services are expensive and take resources away from the other work the County  
 18 could be doing.

19           **a. Clallam County Prosecuting Attorney's Office and Public Defender  
 20 Costs**

21       360. The Clallam County Prosecuting Attorney's Office (PAO) represents the County  
 22 in both criminal and civil matters, and is comprised of five separate divisions, including the

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23       <sup>205</sup> Jesse Major, *Clallam health officer highlights needle exchange's progress*, Peninsula Daily News (Feb. 28,  
 24 2017, 10:50am), <http://www.peninsuladailynews.com/news/clallam-health-officer-highlights-needle-exchanges-progress/>.

25       <sup>206</sup> Christin Hurst, MSW, *Clallam County Health and Human Services Syringe Service Program (SSP)*, Clallam  
 26 County Health & Human Services (Dec. 1, 2015), <http://www.clallam.net/hhs/documents/CCHHSSyringe.pdf>.

27       <sup>207</sup> Jesse Major, *Syringe exchange program to expand to Forks*, Peninsula Daily News (Oct. 12, 2017 2:36pm),  
<http://www.peninsuladailynews.com/news/syringe-exchange-program-to-expand-to-forks/>.

1 Criminal, Civil, and Child Support Divisions. The opioid epidemic has had a significant an  
 2 impact on the PAO.

3 361. For example, the Criminal Division has seen a dramatic rise in the number of  
 4 opioid-related crimes referred to the Division for prosecution. Cases involving charges such as  
 5 violation of the controlled substances act and driving under the influence of opioids are now  
 6 routinely part of the PAO's docket.

7 362. The County is also responsible for paying for public defense costs. Although not  
 8 every criminal prosecution involves a public defender, the majority of them do, and they  
 9 represent a significant and serious cost to the County.

10 363. And, the Civil Division, too, has had its opioid-related caseload increase. For  
 11 example, it routinely handles cases of civil forfeitures related to opioids.

12 364. Family support cases involving child support have also been affected by the  
 13 prevalence of opioid addiction. When children are born with opioid-use disorder or their homes  
 14 are fractured because one or both parents are addicted to opioids, the County often must step in  
 15 to protect the children, provide services, and address the resulting legal implications.

16 365. The Prosecuting Attorney also serves as the *ex officio* Coroner by operation of  
 17 Article IV, Section 4.20 of the Clallam County Home Rule Charter. The increase in opioid-  
 18 related deaths in the County results in greater expense to the Coroner's budget.

19           **b. Clallam County Sheriff's Office**

20 366. The Clallam County Sheriff's Office safeguards lives and property throughout the  
 21 entire County. As a result of the opioid epidemic, the Sheriff's Office devotes considerable  
 22 resources to responding to opioid-related crimes. The Sheriff's deputies regularly encounter  
 23 persons affected by opioid use and abuse, and are exposed to syringes and needles on the job.

24 367. The Sheriff's Office also operates a Drug Take-Back Program; the drop-off  
 25 location at the Sheriff's Office accepts all forms of prescription and illicit drugs. This program  
 26

1 provides a safe, convenient, and responsible way to dispose of prescription opioids and minimize  
 2 the potential for abuse and diversion.

3                   **c. Clallam County Jail**

4         368. The Clallam County Jail has experienced increased incarcerations for individuals  
 5 arrested for opioid-related crimes, primarily burglaries. Jail medical staff also provides treatment  
 6 to inmates for the treatment of opioid dependence. In fact, as noted above, the Clallam County  
 7 jail has been a leader in providing medication-assisted treatment to inmates. Clallam County's  
 8 program began in February 2016, and was the first MAT program inside a jail on the West  
 9 Coast, and for some time it was the only such program in Washington State. Eligible inmates are  
 10 provided with Suboxone treatment beginning in the days prior to release and connected to a  
 11 medical provider who will offer follow-up treatment.

12         369. While Clallam County is committed to offering its inmates this treatment, the  
 13 need for it imposes significant additional costs on the County.

14                   **d. Juvenile & Family Services and District Court**

15         370. Clallam County Juvenile and Family Services provides community supervision,  
 16 Court Services, At-Risk Youth Supervision, Diversion, Detention, CASA (Court Appointed  
 17 Special Advocates), and Truancy Assistance. All juvenile cases filed by the Prosecutor's office  
 18 are processed at Juvenile Services, and cases are heard in the courtroom located at that facility.

19         371. Clallam County Juvenile and Family Services have seen the effects of the opioid  
 20 epidemic primarily in the rising number of children in the dependency system, after opioid abuse  
 21 prevents parents from being able to safely care for their children. The Juvenile Services court  
 22 clerk processes each submitted petition. Once the dependency proceedings have started, the  
 23 children then require foster families, CASA volunteers, and court clerk and staffing hours, as  
 24 well as attorney and court costs. Many children in the dependency system also end up in legal  
 25 problems of their own, including substance abuse, truancy, and criminal behavior. The County's  
 26

1 entire Juvenile Court System has witnessed the direct and indirect effects of the opioid epidemic,  
2 particularly beginning in 2009.

3 372. As noted above, the number of dependency filings has risen sharply against the  
4 background of the opioid epidemic, doubling between 2008 and 2013. Each dependency filing  
5 generates multiple court hearings, requires significant staffing and court resources. In fact, the  
6 number of dependency hearings nearly quadrupled between 2008 and 2013, from 1,031 hearings  
7 to 4,013.

8 373. The increase in opioid abuse also affects Clallam County Juvenile and Family  
9 Services because of its work providing chemical dependency treatment to youth. Juvenile and  
10 Family Services staffers have seen that prescription opioid abuse leads not only to increased  
11 heroin use, as the prescriptions become harder to obtain, but also to increased methamphetamine  
12 use, as the stimulant effects of the latter are sought to counter opioids' effects. The increased  
13 heroin and methamphetamine use results in higher costs to law enforcement, probation,  
14 detention, and treatment.

15 374. The Clallam County district court has been affected by the opioid epidemic as a  
16 result of its increased caseload. Clallam County district court is a state court of limited  
17 jurisdiction that has broad jurisdiction over traffic violations and misdemeanors. For example,  
18 crimes like criminal trespass, possession of drug paraphernalia, generic possession, thefts, and  
19 malicious mischief translate to opioid involvement. The court's costs are directly tied to filings,  
20 and the increased caseload brings increased costs.

21       **3. The Parks, Fair and Facilities Department is also not immune to Defendants'**  
22 **conduct.**

23 375. The County's Parks, Fair and Facilities Department has also been affected by the  
24 opioid epidemic. The Parks Department is tasked with managing parks throughout the County.

25 376. The Parks Department and the people who use the Clallam County parks are  
26 affected by the opioid crisis in a variety of ways, but primarily via exposure to used needles. For

1 example, Parks staff have found used needles and syringes in park restrooms, garbage cans,  
 2 parking lots, and flower beds. Janitorial, maintenance, and park managers must take precautions,  
 3 as exposure to such needles carries a risk of infection from blood-borne pathogens. The safe  
 4 disposal of used needles and syringes requires additional time and resources.

5       **4. The opioid epidemic has also contributed to homelessness in Clallam County.**

6       377. The opioid epidemic has also compounded the issue of homeless in in Clallam  
 7 County. Although the causes of homelessness are multi-faceted and complex, substance abuse is  
 8 both a contributing cause and result of homelessness. Opioid-use disorder is a significant factor  
 9 that prevents individuals from maintaining economic well-being and housing stability.  
 10 Additionally, while the leading cause of death among homeless Americans used to be HIV, it is  
 11 now drug overdose. A study published in JAMA Internal Medicine found that overdoses were  
 12 the leading cause of death among individuals experiencing homelessness in the Boston area. Of  
 13 the overdose deaths, 81% involved opioids.<sup>208</sup>

14       378. In 2005, Clallam County Commissioners established the Clallam County  
 15 Homelessness Task Force (HTF) as an advisory committee to the Board of Commissioners. HTF  
 16 is comprised of twenty-two positions designated for representation of various community  
 17 stakeholders, including Clallam County Health and Human Services, mental health and chemical  
 18 dependency providers, city governments, tribal governments, the law and justice system, the  
 19 business community, the faith community, veterans, youth, and homeless or formerly homeless  
 20 individuals. With input from HTF, Clallam County has been working for over a decade to end  
 21 homelessness in the County. But the opioid epidemic has compounded the issues underlying  
 22 homelessness, and made it immeasurably more difficult for Clallam County to address. As the  
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 26<sup>208</sup> Travis P. Baggett, MD, MPH, Stephen W. Hwang, MD, MPH, James J. O'Connell, MD, et al., *Mortality Among  
 Homeless Adults in Boston, Shifts in Causes of Death Over a 15-Year Period*, 173 (3) JAMA Intern Med 189-95  
 (2013), <https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1556797#qundefined>.

1 County's elected officials, treatment providers, and law enforcement personnel have recognized,  
 2 the opioid epidemic and homelessness are interrelated and thus require collaborative efforts.<sup>209</sup>

3       379. In sum, Clallam County has been and continues to be a leader in responding to the  
 4 opioid crisis. But, its response comes at a significant cost to the County. And, even with its  
 5 robust, proactive approach to the epidemic, the County does not have the enormous resources it  
 6 would take to fully address and end the ongoing crisis.

7 **H. No Federal Agency Action, Including by the FDA, Can Provide the Relief Clallam  
 8 County Seeks Here.**

9       380. The injuries Clallam County has suffered and will continue to suffer cannot be  
 10 addressed by agency or regulatory action. There are no rules the FDA could make or actions the  
 11 agency could take that would provide Clallam County the relief it seeks in this litigation.

12       381. Even if prescription opioids were entirely banned today or only used for the  
 13 intended purpose, thousands of Clallam County residents, and millions of Americans, would  
 14 remain addicted to opioids, and overdoses will continue to claim lives. The Sheriff's Office will  
 15 continue to spend extraordinary resources combatting illegal opioid sales, and the Prosecuting  
 16 Attorney's Office and Clallam County courts will remain burdened with opioid-related crimes  
 17 and dependency hearings. Social services and public health efforts will be stretched thin.

18       382. Regulatory action would do nothing to compensate the County for the money and  
 19 resources it has already expended addressing the impacts of the opioid epidemic and the  
 20 resources it will need in the future. Only this litigation has the ability to provide the County with  
 21 the relief it seeks.

22       383. Furthermore, the costs Clallam County has incurred in responding to the opioid  
 23 crisis and in rendering public services described above are recoverable pursuant to the causes of  
 24 actions raised by the County. Defendants' misconduct alleged herein is not a series of isolated

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 26<sup>209</sup> Rob Ollikainen, *Clallam Board of Health urged to tap more resources on opioid epidemic*, Peninsula Daily  
 News (Mar. 24, 2017, 9:53am), <http://www.peninsuladailynews.com/news/clallam-board-of-health-urged-to-tap-more-resources-on-opioid-epidemic/>.

1 incidents, but instead the result of a sophisticated and complex marketing scheme over the course  
 2 of more than twenty years that has caused a substantial and long-term burden on the municipal  
 3 services provided by the County. In addition, the public nuisance created by Defendants and the  
 4 County's requested relief in seeking abatement further compels Defendants to reimburse and  
 5 compensate Clallam County for substantial costs it has spent addressing the crisis Defendants  
 6 caused.

## 7 V. CLAIMS FOR RELIEF

### 8 COUNT ONE — VIOLATIONS OF THE WASHINGTON CONSUMER 9 PROTECTION ACT, RCW 19.86, *ET SEQ.*

10 384. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
 11 fully set forth herein.

12 385. The Washington Consumer Protection Act is codified at RCW 19.86 *et seq.*  
 13 (CPA). The CPA establishes a comprehensive framework for redressing the violations of  
 14 applicable law, and municipalities of Washington State like Clallam County can enforce the CPA  
 15 and recover damages. RCW 19.86.090. The conduct at issue in this case falls within the scope of  
 16 the CPA.

17 386. The CPA prohibits unfair methods of competition and unfair or deceptive acts or  
 18 practices in the conduct of any trade or commerce. Defendants engaged and continue to engage  
 19 in the same pattern of unfair methods of competition, and unfair and/or deceptive conduct  
 20 pursuant to a common practice of misleading the public regarding the purported benefits and  
 21 risks of opioids.

22 387. Manufacturing Defendants, at all times relevant to this Complaint, directly and/or  
 23 through their control of third parties, violated the CPA by making unfair and/or deceptive  
 24 representations about the use of opioids to treat chronic and non-cancer pain, including to  
 25 physicians and consumers in Clallam County. Each Manufacturing Defendant also omitted or  
 26 concealed material facts and failed to correct prior misrepresentations and omissions about the

1 purported benefits and risks of opioids. In addition, each Manufacturing Defendant's silence  
2 regarding the full risks of opioid use constitutes deceptive conduct prohibited by the CPA.

3 388. Distributor Defendants, at all times relevant to this Complaint, directly and/or  
4 through their control of third parties, violated the CPA by making unfair and/or deceptive  
5 representations about their compliance with their obligations to maintain effective controls  
6 against diversion of prescription opioids and to report suspicious orders. Distributor Defendants  
7 concealed the extent of their opioid distribution in order to avoid the issuance of restrictive  
8 quotas, and manipulated the political process to shield themselves from enforcement actions that  
9 would have stopped shipments of opioids.

10 389. These unfair methods of competition and unfair and/or deceptive acts or practices  
11 in the conduct of trade or commerce were reasonably calculated to deceive Clallam County and  
12 its consumers, and did in fact deceive the County and its consumers. Each Manufacturing  
13 Defendant's misrepresentations, concealments, and omissions continue to this day.

14 390. Clallam County has paid money for health care costs associated with prescription  
15 opioids for chronic pain. The County has also paid significant sums of money treating those  
16 covered by its health insurance for other opioid-related health costs. The Defendants'  
17 misrepresentations have further caused the County to spend substantial sums of money on  
18 increased law enforcement, emergency services, social services, public safety, and other human  
19 services in Clallam County, as described above.

20 391. But for these unfair methods of competition and unfair and/or deceptive acts or  
21 practices in the conduct of trade or commerce, Clallam County would not have incurred the costs  
22 related to the epidemic caused by Defendants, as fully described above.

23 392. Logic, common sense, justice, policy, and precedent indicate Manufacturing  
24 Defendants' unfair and deceptive conduct has caused the damage and harm complained of  
25 herein. Manufacturing Defendants knew or reasonably should have known that their statements  
26 regarding the risks and benefits of opioids were false and misleading, and that their statements

1 were causing harm. Distributor Defendants knew or reasonably should have known that the  
2 proliferation of prescription opioids was causing damage to the County. Thus, the harms caused  
3 by Defendants' unfair and deceptive conduct to Clallam County were reasonably foreseeable,  
4 including the financial and economic losses incurred by the County.

5       393. Furthermore, Clallam County brings this cause of action in its sovereign capacity  
6 for the benefit of the State of Washington. The CPA expressly authorizes local governments to  
7 enforce its provisions and to recover damages for violations of the CPA, and this action is  
8 brought to promote the public welfare of the state and for the common good of the state.

9           394. As a direct and proximate cause of each Defendant's unfair and deceptive  
10 conduct, (i) Clallam County has sustained and will continue to sustain injuries, and (ii) pursuant  
11 to RCW 19.86.090, Clallam County is entitled to actual and treble damages in amounts to be  
12 determined at trial, attorneys' fees and costs, and all other relief available under the CPA.

13       395. The Court should also grant injunctive relief enjoining Defendants from future  
14 violations of the CPA. Defendants' actions, as complained of herein, constitute unfair  
15 competition or unfair, deceptive, or fraudulent acts or practices in violation of the CPA.

## COUNT TWO — PUBLIC NUISANCE

17       396. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
18 fully set forth herein.

19       397. Pursuant to RCW 7.48.010, an actionable nuisance is defined as, *inter alia*,  
20 “whatever is injurious to health or indecent or offensive to the senses . . .”

398. Pursuant to RCW 7.48.130, "A public nuisance is one which affects equally the  
rights of an entire community or neighborhood, although the extent of the damage may be  
unequal."

24       399. Clallam County and its residents have a right to be free from conduct that  
25 endangers their health and safety. Yet Defendants have engaged in conduct which endangers or  
26 injures the health and safety of the residents of the County by their production, promotion,

1 distribution, and marketing of opioids for use by residents of Clallam County and in a manner  
2 that substantially interferes with the welfare of Clallam County.

3       400. Each Defendant has created or assisted in the creation of a condition that is  
4 injurious to the health and safety of Clallam County and its residents, and interferes with the  
5 comfortable enjoyment of life and property of entire communities and/or neighborhoods in the  
6 County.

7       401. Defendants' conduct has directly caused deaths, serious injuries, and a severe  
8 disruption of the public peace, order, and safety. Defendants' conduct is ongoing and continues  
9 to produce permanent and long-lasting damage.

10      402. The health and safety of the residents of Clallam County, including those who  
11 use, have used, or will use opioids, as well as those affected by others' opioid use, are matters of  
12 substantial public interest and of legitimate concern to the County's citizens and its residents.

13      403. Defendants' conduct has affected and continues to affect a substantial number of  
14 people within Clallam County and is likely to continue causing significant harm.

15      404. But for Defendants' actions, opioid use—and, ultimately, misuse and abuse—  
16 would not be as widespread as it is today, and the opioid epidemic that currently exists would  
17 have been averted.

18      405. Logic, common sense, justice, policy, and precedent indicate Defendants' unfair  
19 and deceptive conduct has caused the damage and harm complained of herein. Manufacturing  
20 Defendants knew or reasonably should have known that their statements regarding the risks and  
21 benefits of opioids were false and misleading, and that their false and misleading statements  
22 were causing harm from their continued production and marketing of opioids. Distributor  
23 Defendants knew that the widespread distribution of opioids would endanger the health and  
24 safety of residents of Clallam County. Thus, the public nuisance caused by Defendants to  
25 Clallam County was reasonably foreseeable, including the financial and economic losses  
26 incurred by the County.

406. Furthermore, Clallam County brings this cause of action in its sovereign capacity for the benefit of the State of Washington. The applicable RCW with respect to a public nuisance expressly prohibits the conduct complained of herein, and this action is brought to promote the public welfare of the state and for the common good of the state.

407. In addition, engaging in any business in defiance of a law regulating or prohibiting the same is a nuisance per se under Washington law. Each Defendant's conduct described herein of deceptively marketing or excessively distributing opioids violates RCW 7.48.010 and therefore constitutes a nuisance per se.

408. As a direct and proximate cause of Defendants' conduct creating or assisting in the creation of a public nuisance, Clallam County, its community, and its residents have sustained and will continue to sustain substantial injuries.

409. Pursuant to RCW 7.48.020, Clallam County requests an order providing for abatement of the public nuisance that each Defendant has created or assisted in the creation of, and enjoining Defendants from future violations of RCW 7.48.010.

410. Clallam County also seeks the maximum statutory and civil penalties permitted by law as a result of the public nuisance created by Defendants.

### **COUNT THREE — NEGLIGENCE**

411. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

412. Under Washington law, a cause of action arises for negligence when a defendant owes a duty to a plaintiff and breaches that duty, and proximately causes the resulting injury. *Iwai v. State*, 129 Wn. 2d 84, 96, 915 P.2d 1089 (1996).

413. Each Defendant owed a duty of care to Clallam County, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

414. In violation of this duty, Defendants failed to take reasonable steps to prevent the misuse, abuse, and over-prescription of opioids in Clallam County by misrepresenting the risks and benefits associated with opioids and by distributing dangerous quantities of opioids.

415. As set forth above, Manufacturing Defendants' misrepresentations include falsely claiming that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing more opioids was appropriate when patients presented symptoms of addiction, falsely claiming that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that doctors and patients could increase opioid usage indefinitely without added risk, deceptively marketing that purported abuse-deterrent technology could curb misuse and addiction, and falsely claiming that long-term opioid use could actually restore function and improve a patient's quality of life. Each of these misrepresentations made by Defendants violated the duty of care to Clallam County.

416. Distributor Defendants negligently distributed enormous quantities of potent narcotics and failed to report such distributions. Distributor Defendants violated their duty of care by moving these dangerous products into Clallam County in such quantities, facilitating diversion, misuse, and abuse of opioids.

417. As a direct and proximate cause of Defendants' unreasonable and negligent conduct, Plaintiff has suffered and will continue to suffer harm, and is entitled to damages in an amount determined at trial.

## **COUNT FOUR — GROSS NEGLIGENCE**

418. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if fully set forth herein.

419. As set forth above, each Defendant owed a duty of care to Clallam County, including but not limited to taking reasonable steps to prevent the misuse, abuse, and over-prescription of opioids.

1       420. In violation of this duty, each Defendant failed to take reasonable steps to prevent  
 2 the misuse, abuse, and over-prescription of opioids in Clallam County by misrepresenting the  
 3 risks and benefits associated with opioids.

4       421. In addition, each Defendant knew or should have known, and/or recklessly  
 5 disregarded, that the opioids they manufactured, promoted, and distributed were being used for  
 6 unintended uses.

7       422. For instance, Defendants failed to exercise slight care to Clallam County by, *inter*  
 8 *alia*, failing to take appropriate action to stop opioids from being used for unintended purposes.  
 9 Furthermore, despite each Defendant's actual or constructive knowledge of the wide  
 10 proliferation and dissemination of opioids in Clallam County, Defendants took no action to  
 11 prevent the abuse and diversion of their pharmaceutical drugs. In fact, Manufacturing Defendants  
 12 promoted and actively targeted doctors and their patients through training their sales  
 13 representatives to encourage doctors to prescribe more prescription opioids.

14       423. Manufacturing Defendants' misrepresentations further include falsely claiming  
 15 that the risk of opioid addiction was low, falsely instructing doctors and patients that prescribing  
 16 more opioids was appropriate when patients presented symptoms of addiction, falsely claiming  
 17 that risk-mitigation strategies could safely address concerns about addiction, falsely claiming that  
 18 doctors and patients could increase opioid usage indefinitely without added risk, deceptively  
 19 marketing that purported abuse-deterring technology could curb misuse and addiction, and  
 20 falsely claiming that long-term opioid use could actually restore function and improve a patient's  
 21 quality of life. Each of these misrepresentations made by Manufacturing Defendants violated the  
 22 duty of care to Clallam County, in a manner that is substantially and appreciably greater than  
 23 ordinary negligence.

24       424. Distributor Defendants continued to funnel enormous quantities of potent opioids  
 25 into Clallam County, long after they knew that these products were being misused, abused, and  
 26 diverted. By permitting the movement of massive amounts of dangerous narcotics into Clallam

1 County, Distributor Defendants endangered the health and safety of Clallam County residents, in  
2 a manner that is substantially and appreciably greater than ordinary negligence.

3 425. As a direct and proximate cause of each Defendant's gross negligence, Clallam  
4 County has suffered and will continue to suffer harm, and is entitled to damages in an amount  
5 determined at trial.

6 **COUNT FIVE — UNJUST ENRICHMENT**

7 426. Plaintiff repeats, reasserts, and incorporates the allegations contained above as if  
8 fully set forth herein.

9 427. Each Defendant was required to take reasonable steps to prevent the misuse,  
10 abuse, and over-prescription of opioids.

11 428. Rather than prevent or mitigate the wide proliferation of opioids into Clallam  
12 County, each Defendant instead chose to place its monetary interests first and each Defendant  
13 profited immensely from supplying prescription opioids to Clallam County.

14 429. Each Defendant also failed to maintain effective controls against the unintended  
15 and illegal use of their prescription opioids, again choosing instead to place its monetary interests  
16 first.

17 430. Each Defendant therefore received a benefit from the sale and distribution of  
18 prescription opioids to and in Clallam County, and these Defendants have been unjustly enriched  
19 at the expense of Clallam County.

20 431. As a result, Clallam County is entitled to damages on its unjust enrichment claim  
21 in an amount to be proven at trial.

22 **COUNT SIX — VIOLATIONS OF THE RACKETEER INFLUENCED AND  
23 CORRUPT ORGANIZATIONS ACT (“RICO”), 18 U.S.C. § 1961, ET SEQ.**

24 432. Plaintiff hereby incorporates by reference the allegations contained in the  
25 preceding paragraphs of this complaint.

1       433. This claim is brought by Clallam County against each Defendant for actual  
2 damages, treble damages, and equitable relief under 18 U.S.C. § 1964 for violations of 18 U.S.C.  
3 § 1961, *et seq.*

4       434. At all relevant times, each Defendant is and has been a “person” within the  
5 meaning of 18 U.S.C. § 1961(3), because they are capable of holding, and do hold, “a legal or  
6 beneficial interest in property.”

7       435. Plaintiff is a “person,” as that term is defined in 18 U.S.C. § 1961(3), and has  
8 standing to sue as it was and is injured in its business and/or property as a result of the  
9 Defendants’ wrongful conduct described herein.

10       436. Section 1962(c) makes it “unlawful for any person employed by or associated  
11 with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce,  
12 to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through  
13 a pattern of racketeering activity . . . ” 18 U.S.C. § 1962(c).

14       437. Section 1962(d) makes it unlawful for “any person to conspire to violate” Section  
15 1962(c), among other provisions. *See* 18 U.S.C. § 1962(d).

16       438. Each Defendant conducted the affairs of an enterprise through a pattern of  
17 racketeering activity, in violation of 18 U.S.C. § 1962(c) and § 1962(d).

18       **A. Description of the Defendants’ Enterprises**

19       439. RICO defines an enterprise as “any individual, partnership, corporation,  
20 association, or other legal entity, and any union or group of individuals associated in fact  
21 although not a legal entity.” 18 U.S.C. § 1961(4).

22       440. Under 18 U.S.C. § 1961(4) a RICO “enterprise” may be an association-in-fact  
23 that, although it has no formal legal structure, has (i) a common purpose, (ii) relationships among  
24 those associated with the enterprise, and (iii) longevity sufficient to pursue the enterprise’s  
25 purpose. *See Boyle v. United States*, 556 U.S. 938, 946 (2009).

1       441. Defendants formed two such association-in-fact enterprises—referred to herein as  
 2 “the Promotion Enterprise” and “the Diversion Enterprise.”

3       442. The Promotion Enterprise consists of the Manufacturing Defendants, Front  
 4 Groups, and KOLs. In particular, the Enterprise consists of (a) Defendant Purdue, including its  
 5 employees and agents, (b) Defendant Endo, including its employees and agents, (c) Defendant  
 6 Janssen, including its employees and agents, (d) Defendant Cephalon, including its employees  
 7 and agents, (e) Defendant Actavis, including its employees and agents, and (f) Defendant  
 8 Mallinckrodt, including its employees and agents (collectively, “Manufacturing Defendants”);  
 9 certain front groups described above, including but not limited to (a) the American Pain  
 10 Foundation, including its employees and agents, (b) the American Academy of Pain Medicine,  
 11 including its employees and agents, and (c) the American Pain Society, including its employees  
 12 and agents (collectively, the “Front Groups”); and certain Key Opinion Leaders, including but  
 13 not limited to (a) Dr. Russell Portenoy, (b) Dr. Perry Fine, (c) Dr. Lynn Webster, and (d) Dr.  
 14 Scott Fishman (collectively, the “KOLs”). The entities in the Promotion Enterprise acted in  
 15 concert to create demand for prescription opioids.

16       443. Alternatively, each of the above-named Manufacturing Defendants and Front  
 17 Groups constitutes a single legal entity “enterprise” within the meaning of 18 U.S.C. § 1961(4),  
 18 through which the members of the enterprise conducted a pattern of racketeering activity. The  
 19 separate legal status of each member of the Enterprise facilitated the fraudulent scheme and  
 20 provided a hoped-for shield from liability for Defendants and their co-conspirators.

21       444. Alternatively, each of the Manufacturing Defendants, together with the  
 22 Distributor Defendants, the Front Groups, and the KOLs, constitute separate, associated-in-fact  
 23 Enterprises within the meaning of 18 U.S.C. § 1961(4).

24       445. The Diversion Enterprise consists of all Defendants. In particular, the Enterprise  
 25 consists of (a) Defendant Purdue, including its employees and agents, (b) Defendant Endo,  
 26 including its employees and agents, (c) Defendant Janssen, including its employees and agents,

1 (d) Defendant Cephalon, including its employees and agents, (e) Defendant Actavis, including its  
 2 employees and agents, (f) Defendant Mallinckrodt, including its employees and agents, (g)  
 3 Defendant AmerisourceBergen, including its employees and agents, (h) Defendant Cardinal  
 4 Health, including its employees and agents, and (i) Defendant McKesson, including its  
 5 employees and agents (collectively, “Defendants”).

6       446. The CSA and its implementing regulations require all manufacturers and  
 7 distributors of controlled substances, including opioids, to maintain a system to identify and  
 8 report suspicious orders, including orders of unusual size or frequency, or orders deviating from  
 9 a normal pattern, and maintain effective controls against diversion of controlled substances. *See*  
 10 21 U.S.C. § 823; 21 C.F.R. §1301.74(b). The Manufacturing Defendants and the Distributor  
 11 Defendants alike are required to become “registrants” under the CSA, 21 U.S.C. § 823(a)-(b),  
 12 and its implementing regulations, which provide that “[e]very person who manufactures,  
 13 distributes, dispenses, imports, or exports any controlled substance. . . shall obtain a  
 14 registration[.]” 21 C.F.R. § 1301.11(a). Defendants’ duties as registrants include reporting  
 15 suspicious orders of controlled substances, which are defined as including “orders of unusual  
 16 size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 21  
 17 C.F.R. § 1301.74(b).

18       447. The Manufacturing Defendants carried out the Diversion Enterprise by  
 19 incentivizing and supplying suspicious sales of opioids, despite their knowledge that their  
 20 opioids were being diverted to illicit use, and by failing to notify the DEA of such suspicious  
 21 orders as required by law. The Distributor Defendants carried out the Diversion Enterprise by  
 22 failing to maintain effective controls against diversion, intentionally evading their obligation to  
 23 report suspicious orders to the DEA, and conspiring to prevent limits on the prescription opioids  
 24 they were oversupplying to communities like Plaintiff.

25       448. The Promotion Enterprise is an ongoing and continuing business organization  
 26 consisting of “persons” within the meaning of 18 U.S.C. § 1961(3) that created and maintained

1 systematic links for a common purpose: to sell highly addictive opioids for treatment of chronic  
2 pain while knowing that opioids have little or no demonstrated efficacy for such pain and have  
3 significant risk of addiction, overdose, and death.

4 449. The Distribution Enterprise is an ongoing and continuing business organization  
5 consisting of “persons” within the meaning of 18 U.S.C. § 1961(3) that created and maintained  
6 systematic links for a common purpose: to distribute highly addictive opioids in quantities that  
7 far exceeded amounts that could reasonably be considered medically necessary.

8 450. To accomplish these purposes, the Promotion Enterprise engaged in a  
9 sophisticated, well-developed, and fraudulent marketing scheme designed to increase the  
10 prescription rate for Defendants’ opioid medications (the “Promotion Scheme”), and the  
11 Diversion Enterprise carried out a scheme to systematically disregard, avoid, or frustrate the  
12 monitoring and reporting requirements intended to prevent the widespread distribution of  
13 dangerous controlled substances (the “Diversion Scheme”). The Promotion Scheme and the  
14 Diversion Scheme are collectively referred to as the “Schemes.”

15 **B. The Enterprises Sought to Fraudulently Increase Defendants’ Profits and Revenues**

16 451. At all relevant times, each Defendant was aware of the conduct of the Enterprises,  
17 was a knowing and willing participant in that conduct, and reaped profits from that conduct in  
18 the form of increased sales and distribution of prescription opioids. In addition, the Front Groups  
19 and KOLs received direct payments from the Manufacturing Defendants in exchange for their  
20 role in the Promotion Enterprise, and to advance the Promotion Enterprise’s fraudulent  
21 marketing scheme.

22 452. The Enterprises engaged in, and their activities affected, interstate and foreign  
23 commerce because they involved commercial activities across state boundaries, including but not  
24 limited to: (1) the marketing, promotion, and distribution of prescription opioids; (2) advocacy at  
25 the state and federal level for change in the law governing the use and prescription of  
26 prescription opioids; (3) the issuance of prescriptions and prescription guidelines for opioids; (4)

1 the issuance of fees, bills, and statements demanding payment for prescriptions of opioids; (5)  
 2 payments, rebates, and chargebacks between Defendants; and (6) the creation of documents,  
 3 reports, and communications related to Defendants' reporting requirements under the CSA and  
 4 its implementing regulations.

5       453. The persons engaged in the Enterprises are systematically linked through  
 6 contractual relationships, financial ties, and continuing coordination of activities, as spearheaded  
 7 by Defendants. With respect to the Promotion Enterprise, each Manufacturing Defendant funded  
 8 and directed the operations of the KOLs and the Front Groups; in fact, the board of directors of  
 9 each of the Front Groups are and were full of doctors who were on the Manufacturing  
 10 Defendants' payrolls, either as consultants or speakers at medical events. Moreover, each  
 11 Manufacturing Defendant coordinated and, at times, co-funded their activities in furtherance of  
 12 the goals of the Enterprise. This coordination can also be inferred through the consistent  
 13 misrepresentations described below. With respect to the Diversion Enterprise, Defendants were  
 14 financially linked through a system of payments, rebates, and chargebacks.

15       454. In the Promotion Enterprise, there is regular communication between each  
 16 Manufacturing Defendant, each of the Front Groups, and each KOL in which information  
 17 regarding the Defendants' scheme to increase opioid prescriptions is shared. Typically, this  
 18 communication occurred, and continues to occur, through the use of the wires and the mail in  
 19 which Manufacturing Defendants, the Front Groups, and the KOL share information regarding  
 20 the operation of the Promotion Enterprise.

21       455. In the Diversion Enterprise, there is regular communication between each  
 22 Defendant in which information regarding the Defendants' scheme to oversupply opioids and  
 23 avoid restrictive regulations or quotas is shared. Typically, this communication occurred, and  
 24 continues to occur, through the use of the wires and the mail in which Defendants share  
 25 information regarding the operation of the Diversion Enterprise.  
 26

1       456. The Enterprises functioned as continuing units for the purposes of executing the  
2 Schemes, and when issues arose during the Schemes, each member of the Enterprises agreed to  
3 take actions to hide the Schemes and the existence of the Enterprises.

4       457. Each Defendant participated in the operation and management of the Enterprises  
5 by directing its affairs as described herein.

6       458. While Defendants participate in, and are members of, the Enterprises, they have  
7 an existence separate from the Enterprises, including distinct legal statuses, affairs, offices and  
8 roles, officers, directors, employees, and individual personhood.

9       459. Each Manufacturing Defendant orchestrated the affairs of the Promotion  
10 Enterprise and exerted substantial control over the Promotion Enterprise by, at least: (1) making  
11 misleading statements about the purported benefits, efficacy, and risks of opioids to doctors,  
12 patients, the public, and others, in the form of telephonic and electronic communications, CME  
13 programs, medical journals, advertisements, and websites; (2) employing sales representatives to  
14 promote the use of opioid medications; (3) purchasing and utilizing sophisticated marketing data  
15 (e.g., IMS data) to coordinate and refine the Promotion Scheme; (4) employing doctors to serve  
16 as speakers at or attend all-expense paid trips to programs emphasizing the benefits of  
17 prescribing opioid medications; (5) funding, controlling, and operating the Front Groups,  
18 including the American Pain Foundation and the Pain & Policy Studies Group; (6) sponsoring  
19 CME programs that claimed that opioid therapy has been shown to reduce pain and depressive  
20 symptoms; (7) supporting and sponsoring guidelines indicating that opioid medications are  
21 effective and can restore patients' quality of life; (8) retaining KOLs to promote the use of  
22 opioids; and (9) concealing the true nature of their relationships with the other members of the  
23 Promotion Scheme, and the Promotion Enterprise, including the Front Groups and the KOLs.

24       460. The Front Groups orchestrated the affairs of the Promotion Enterprise and exerted  
25 substantial control over the Promotion Enterprise by, at least: (1) making misleading statements  
26 about the purported benefits, efficacy, and low risks of opioids described herein; (2) holding

1 themselves out as independent advocacy groups, when in fact their operating budgets are entirely  
 2 comprised of contributions from opioid drug manufacturers; (3) publishing treatment guidelines  
 3 that advised the prescription of opioids; (4) sponsoring medical education programs that touted  
 4 the benefits of opioids to treat chronic pain while minimizing and trivializing their risks; and (5)  
 5 concealing the true nature of their relationship with the other members of the Promotion  
 6 Enterprise.

7       461. The KOLs orchestrated the affairs of the Promotion Enterprise and exerted  
 8 substantial control over the Promotion Enterprise by, at least: (1) making misleading statements  
 9 about the purported benefits, efficacy, and low risks of opioids; (2) holding themselves out as  
 10 independent, when in fact they are systematically linked to and funded by opioid drug  
 11 manufacturers; and (3) concealing the true nature of their relationship with the other members of  
 12 the Promotion Enterprise.

13       462. Without the willing participation of each member of the Promotion Enterprise, the  
 14 Promotion Scheme and the Promotion Enterprise's common course of conduct would not have  
 15 been successful.

16       463. Each Distributor Defendant orchestrated the affairs of the Diversion Enterprise  
 17 and exerted substantial control over the Diversion Enterprise by, at least: (1) refusing or failing  
 18 to identify, investigate, or report suspicious orders of opioids to the DEA; (2) providing the  
 19 Manufacturing Defendants with data regarding their prescription opioid sales, including purchase  
 20 orders and ship notices; (3) accepting payments from the Manufacturing Defendants in the form  
 21 of rebates and/or chargebacks; (4) filling suspicious orders for prescription opioids despite  
 22 having identified them as suspicious and knowing opioids were being diverted into the illicit  
 23 drug market; (5) working with other members of the Enterprise through groups like the  
 24 Healthcare Distribution Alliance to ensure the free flow of opioids, including by supporting  
 25 limits on the DEA's ability to use immediate suspension orders; and (6) concealing the true  
 26 nature of their relationships with the other members of the Diversion Enterprise.

1       464. Each Manufacturing Defendant orchestrated the affairs of the Diversion  
 2 Enterprise and exerted substantial control over the Diversion Enterprise by, at least: (1) refusing  
 3 or failing to identify, investigate, or report suspicious orders of opioids to the DEA; (2) obtaining  
 4 from the Distributor Defendants data regarding their prescription opioid sales, including  
 5 purchase orders and ship notices; (3) providing payments to the Distributor Defendants in the  
 6 form of rebates and/or chargebacks; (4) working with other members of the Diversion Enterprise  
 7 through groups like the Healthcare Distribution Alliance to ensure the free flow of opioids,  
 8 including by supporting limits on the DEA's ability to use immediate suspension orders; and (5)  
 9 concealing the true nature of their relationships with the other members of the Diversion  
 10 Enterprise.

11       465. Without the willing participation of each member of the Diversion Enterprise, the  
 12 Diversion Scheme and the Diversion Enterprise's common course of conduct would not have  
 13 been successful.

14 **C. Predicate Acts: Mail and Wire Fraud**

15       466. To carry out, or attempt to carry out, the Schemes, the members of the  
 16 Enterprises, each of whom is a person associated-in-fact with the Enterprises, did knowingly  
 17 conduct or participate in, directly or indirectly, the affairs of the Enterprises through a pattern of  
 18 racketeering activity within the meaning of 18 U.S.C. §§ 1961(1), 1961(5) and 1962(c), and  
 19 employed the use of the mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud)  
 20 and § 1343 (wire fraud).

21       467. Specifically, the members of the Enterprises have committed, conspired to  
 22 commit, and/or aided and abetted in the commission of, at least two predicate acts of  
 23 racketeering activity (i.e., violations of 18 U.S.C. §§ 1341 and 1343), within the past ten years.

24       468. The multiple acts of racketeering activity which the members of the Enterprises  
 25 committed, or aided or abetted in the commission of, were related to each other, posed a threat of  
 26 continued racketeering activity, and therefore constitute a "pattern of racketeering activity."

1       469. The racketeering activity was made possible by the Enterprises' regular use of the  
 2 facilities, services, distribution channels, and employees of the Enterprises.

3       470. The members of the Enterprises participated in the Schemes by using mail,  
 4 telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

5       471. The members of the Enterprises used, directed the use of, and/or caused to be  
 6 used, thousands of interstate mail and wire communications in service of their Schemes through  
 7 common misrepresentations, concealments, and material omissions.

8       472. In devising and executing the illegal Schemes, the members of the Enterprises  
 9 devised and knowingly carried out a material scheme and/or artifice to defraud Plaintiff and the  
 10 public to obtain money by means of materially false or fraudulent pretenses, representations,  
 11 promises, or omissions of material facts.

12       473. For the purpose of executing the illegal Schemes, the members of the Enterprises  
 13 committed these racketeering acts, which number in the thousands, intentionally and knowingly  
 14 with the specific intent to advance the illegal Schemes.

15       474. The Enterprises' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but  
 16 are not limited to:

17       A. Mail Fraud: The members of the Enterprises violated 18 U.S.C. § 1341 by  
 18 sending or receiving, or by causing to be sent and/or received, fraudulent materials  
 19 via U.S. mail or commercial interstate carriers for the purpose of selling and  
 distributing excessive quantities of highly addictive opioids.

20       B. Wire Fraud: The members of the Enterprises violated 18 U.S.C. § 1343 by  
 21 transmitting and/or receiving, or by causing to be transmitted and/or received,  
 22 fraudulent materials by wire for the purpose of selling and distributing excessive  
 23 quantities of highly addictive opioids.

24       475. The Manufacturing Defendants falsely and misleadingly used the mails and wires  
 25 in violation of 18 U.S.C. § 1341 and § 1343. Illustrative and non-exhaustive examples include  
 26 the following: Defendant Purdue's (1) May 31, 1996 press release announcing the release of  
 OxyContin and indicating that the fear of OxyContin's addictive properties was exaggerated; (2)

1 1990 promotional video in which Dr. Portenoy, a paid Purdue KOL, understated the risk of  
2 opioid addiction; (3) 1998 promotional video which misleadingly cited a 1980 NEJM letter in  
3 support of the use of opioids to treat chronic pain; (4) statements made on its 2000 “Partners  
4 Against Pain” website which claimed that the addiction risk of OxyContin was very low; (5)  
5 literature distributed to physicians which misleadingly cited a 1980 NEJM letter in support of the  
6 use of opioids to treat chronic pain; (6) August 2001 statements to Congress by Purdue  
7 Executive Vice President and Chief Operating Officer Michael Friedman regarding the value of  
8 OxyContin in treating chronic pain; (7) patient brochure entitled “A Guide to Your New Pain  
9 Medicine and How to Become a Partner Against Pain” indicating that OxyContin is non-  
10 addicting; (8) 2001 statement by Senior Medical Director for Purdue, Dr. David Haddox,  
11 indicating that the ‘legitimate’ use of OxyContin would not result in addiction; (9) multiple sales  
12 representatives’ communications regarding the low risk of addiction associated with opioids;  
13 (10) statements included in promotional materials for opioids distributed to doctors via the mail  
14 and wires; (11) statements in a 2003 Patient Information Guide distributed by Purdue indicating  
15 that addiction to opioid analgesics in properly managed patients with pain has been reported to  
16 be rare; (12) telephonic and electronic communications to doctors and patients indicating that  
17 signs of addiction in the case of opioid use are likely only the signs of under-treated pain; (13)  
18 statements in Purdue’s Risk Evaluation and Mitigation Strategy for OxyContin indicating that  
19 drug-seeking behavior on the part of opioid patients may, in fact, be pain-relief seeking behavior;  
20 (14) statements made on Purdue’s website and in a 2010 “Dear Healthcare Professional” letter  
21 indicating that opioid dependence can be addressed by dosing methods such as tapering; (15)  
22 statements included in a 1996 sales strategy memo indicating that there is no ceiling dose for  
23 opioids for chronic pain; (16) statements on its website that abuse-resistant products can prevent  
24 opioid addiction; (17) statements made in a 2012 series of advertisements for OxyContin  
25 indicating that long-term opioid use improves patients’ function and quality of life; (18)  
26 statements made in advertising and a 2007 book indicating that pain relief from opioids improve

1 patients' function and quality of life; (19) telephonic and electronic communications by its sales  
 2 representatives indicating that opioids will improve patients' function; and (20) electronic and  
 3 telephonic communications concealing its relationship with the other members of the  
 4 Enterprises.

5       476. Defendant Endo Pharmaceuticals, Inc. also made false or misleading claims in  
 6 violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made,  
 7 beginning in at least 2009, on an Endo-sponsored website, PainKnowledge.com, indicating that  
 8 patients who take opioids as prescribed usually do not become addicted; (2) statements made on  
 9 another Endo-sponsored website, PainAction.com, indicating that most chronic pain patients do  
 10 not become addicted to opioid medications; (3) statements in pamphlets and publications  
 11 described by Endo indicating that most people who take opioids for pain relief do not develop an  
 12 addiction; (4) statements made on the Endo-run website, Opana.com, indicating that opioid use  
 13 does not result in addiction; (5) statements made on the Endo-run website, Opana.com,  
 14 indicating that opioid dependence can be addressed by dosing methods such as tapering; (6)  
 15 statements made on its website, PainKnowledge.com, that opioid dosages could be increased  
 16 indefinitely; (7) statements made in a publication entitled "Understanding Your Pain: Taking  
 17 Oral Opioid Analgesics" suggesting that opioid doses can be increased indefinitely; (8)  
 18 electronic and telephonic communications to its sales representatives indicating that the formula  
 19 for its medicines is 'crush resistant;' (9) statements made in advertisements and a 2007 book  
 20 indicating that pain relief from opioids improves patients' function and quality of life; (10)  
 21 telephonic and electronic communications by its sales representatives indicating that opioids will  
 22 improve patients' function; and (11) telephonic and electronic communications concealing its  
 23 relationship with the other members of the Enterprises.

24       477. Defendant Janssen made false or misleading claims in violation of 18 U.S.C. §  
 25 1341 and § 1343 including but not limited to: (1) statements on its website,  
 26 PrescribeResponsibly.com, indicating that concerns about opioid addiction are overestimated; (2)

1 statements in a 2009 patient education guide claiming that opioids are rarely addictive when used  
 2 properly; (3) statements included on a 2009 Janssen-sponsored website promoting the concept of  
 3 opioid pseudoaddiction; (4) statements on its website, PrescribeResponsibly.com, advocating the  
 4 concept of opioid pseudoaddiction; (5) statements on its website, PrescribeResponsibly.com,  
 5 indicating that opioid addiction can be managed; (6) statements in its 2009 patient education  
 6 guide indicating the risks associated with limiting the dosages of pain medicines; (7) telephonic  
 7 and electronic communications by its sales representatives indicating that opioids will improve  
 8 patients' function; and (8) telephonic and electronic communications concealing its relationship  
 9 with the other members of the Enterprises.

10       478. The American Academic of Pain Medicine made false or misleading claims in  
 11 violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements made in a  
 12 2009 patient education video entitled "Finding Relief: Pain Management for Older Adults"  
 13 indicating the opioids are rarely addictive; and (2) telephonic and electronic communications  
 14 concealing its relationship with the other members of the Promotion Enterprise.

15       479. The American Pain Society Quality of Care Committee made a number of false or  
 16 misleading claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) a  
 17 May 31, 1996 press release in which the organization claimed there is very little risk of addiction  
 18 from the proper use of drugs for pain relief; and (2) telephonic and electronic communications  
 19 concealing its relationship with the other members of the Promotion Enterprise.

20       480. The American Pain Foundation ("APF") made a number of false and misleading  
 21 claims in violation of 18 U.S.C. § 1341 and § 1343 including but not limited to: (1) statements  
 22 made by an APF Executive Director to Congress indicating that opioids only rarely lead to  
 23 addiction; (2) statements made in a 2002 amicus curiae brief filed with an Ohio appeals court  
 24 claiming that the risk of abuse does not justify restricting opioid prescriptions for the treatment  
 25 of chronic pain; (3) statements made in a 2007 publication entitled "Treatment Options: A Guide  
 26 for People Living with Pain" indicating that the risks of addiction associated with opioid

1 prescriptions have been overstated; (4) statements made in a 2002 court filing indicating that  
 2 opioid users are not “actual addicts”; (5) statements made in a 2007 publication entitled  
 3 “Treatment Options: A Guide for People Living with Pain” indicating that even physical  
 4 dependence on opioids does not constitute addiction; (6) claims on its website that there is no  
 5 ceiling dose for opioids for chronic pain; (7) statements included in a 2011 guide indicating that  
 6 opioids can improve daily function; and (8) telephonic and electronic communications  
 7 concealing its relationship with the other members of the Promotion Enterprise.

8       481. The KOLs, including Drs. Russell Portenoy, Perry Fine, Scott Fishman, and Lynn  
 9 Webster, made a number of misleading statements in the mail and wires in violation of 18 U.S.C.  
 10 § 1341 and § 1343, described above, including statements made by Dr. Portenoy in a  
 11 promotional video indicating that the likelihood of addiction to opioid medications is extremely  
 12 low. Indeed, Dr. Portenoy has since admitted that his statements about the safety and efficacy of  
 13 opioids were false.

14       482. The Manufacturing Defendants and Distributor Defendants falsely and  
 15 misleadingly used the mails and wires in violation of 18 U.S.C. § 1341 and § 1343. Illustrative  
 16 and non-exhaustive examples include the following: (1) the transmission of documents and  
 17 communications regarding the sale, shipment, and delivery of excessive quantities of  
 18 prescription opioids, including invoices and shipping records; (2) the transmission of documents  
 19 and communications regarding their requests for higher aggregate production quotas, individual  
 20 manufacturing quotas, and procurement quotas; (3) the transmission of reports to the DEA that  
 21 did not disclose suspicious orders as required by law; (4) the transmission of documents and  
 22 communications regarding payments, rebates, and chargebacks; (5) the transmission of the actual  
 23 payments, rebates, and chargebacks themselves; (6) correspondence between Defendants and  
 24 their representatives in front groups and trade organizations regarding efforts to curtail  
 25 restrictions on opioids and hobble DEA enforcement actions; (7) the submission of false and  
 26 misleading certifications required annually under various agreements between Defendants and

1 federal regulators; and (8) the shipment of vast quantities of highly addictive opioids. Defendants  
 2 also communicated by U.S. mail, by interstate facsimile, and by interstate electronic mail and  
 3 with various other affiliates, regional offices, regulators, distributors, and other third-party  
 4 entities in furtherance of the scheme.

5       483. In addition, the Distributor Defendants misrepresented their compliance with laws  
 6 requiring them to identify, investigate, and report suspicious orders of prescription opioids and/or  
 7 diversion into the illicit market. At the same time, the Distributor Defendants misrepresented the  
 8 effectiveness of their monitoring programs, their ability to detect suspicious orders, their  
 9 commitment to preventing diversion of prescription opioids, and their compliance with  
 10 regulations regarding the identification and reporting of suspicious orders of prescription opioids.

11       484. The mail and wire transmissions described herein were made in furtherance of  
 12 Defendants' Schemes and common course of conduct designed to sell drugs that have little or no  
 13 demonstrated efficacy for the pain they are purported to treat in the majority of persons  
 14 prescribed them; increase the prescription rate for opioid medications; and popularize the  
 15 misunderstanding that the risk of addiction to prescription opioids is low when used to treat  
 16 chronic pain, and to deceive regulators and the public regarding Defendants' compliance with  
 17 their obligations to identify and report suspicious orders of prescription opioids, while  
 18 Defendants intentionally enabled millions of prescription opioids to be deposited into  
 19 communities across the United States, including in Clallam County. Defendants' scheme and  
 20 common course of conduct was intended to increase or maintain high quotas for the manufacture  
 21 and distribution of prescription opioids and their corresponding high profits for all Defendants.

22       485. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate  
 23 wire facilities have been deliberately hidden, and cannot be alleged without access to  
 24 Defendants' books and records. However, Plaintiff has described the types of predicate acts of  
 25 mail and/or wire fraud, including certain specific fraudulent statements and specific dates upon  
 26

1 which, through the mail and wires, Defendants engaged in fraudulent activity in furtherance of  
 2 the Schemes.

3       486. The members of the Enterprises have not undertaken the practices described  
 4 herein in isolation, but as part of a common scheme and conspiracy. In violation of 18 U.S.C. §  
 5 1962(d), the members of the Enterprises conspired to violate 18 U.S.C. § 1962(c), as described  
 6 herein. Various other persons, firms, and corporations, including third-party entities and  
 7 individuals not named as defendants in this Complaint, have participated as co-conspirators with  
 8 Defendants and the members of the Enterprises in these offenses and have performed acts in  
 9 furtherance of the conspiracy to increase or maintain revenue, increase market share, and/or  
 10 minimize losses for the Defendants and their named and unnamed co-conspirators throughout the  
 11 illegal scheme and common course of conduct.

12       487. The members of the Enterprises aided and abetted others in the violations of the  
 13 above laws.

14       488. To achieve their common goals, the members of the Enterprises hid from Plaintiff  
 15 and the public: (1) the fraudulent nature of the Manufacturing Defendants' marketing scheme;  
 16 (2) the fraudulent nature of statements made by Defendants and on behalf of Defendants  
 17 regarding the efficacy of and risk of addiction associated with prescription opioids; (3) the  
 18 fraudulent nature of the Distributor Defendants' representations regarding their compliance with  
 19 requirements to maintain effective controls against diversion and report suspicious orders of  
 20 opioids; and (4) the true nature of the relationship between the members of the Enterprises.

21       489. Defendants and each member of the Enterprises, with knowledge and intent,  
 22 agreed to the overall objectives of the Schemes and participated in the common course of  
 23 conduct. Indeed, for the conspiracy to succeed, each of the members of the Enterprises and their  
 24 co-conspirators had to agree to conceal their fraudulent scheme.

1       490. The members of the Enterprises knew, and intended that, Plaintiff and the public  
2 would rely on the material misrepresentations and omissions made by them and suffer damages  
3 as a result.

4       491. As described herein, the members of the Enterprises engaged in a pattern of  
5 related and continuous predicate acts for years. The predicate acts constituted a variety of  
6 unlawful activities, each conducted with the common purpose of obtaining significant monies  
7 and revenues from Plaintiff and the public based on their misrepresentations and omissions.

8       492. The predicate acts also had the same or similar results, participants, victims, and  
9 methods of commission.

10      493. The predicate acts were related and not isolated events.

11      494. The true purposes of Defendants' Schemes were necessarily revealed to each  
12 member of the Enterprises. Nevertheless, the members of the Enterprises continued to  
13 disseminate misrepresentations regarding the nature of prescription opioids and the functioning  
14 of the Schemes.

15      495. Defendants' fraudulent concealment was material to Plaintiff and the public. Had  
16 the members of the Enterprises disclosed the true nature of prescription opioids and their  
17 excessive distribution, Clallam County would not have acted as it did or incurred the substantial  
18 costs in responding to the crisis caused by Defendants' conduct.

19      496. The pattern of racketeering activity described above is currently ongoing and  
20 open-ended, and threatens to continue indefinitely unless this Court enjoins the racketeering  
21 activity.

22 **D. Clallam County Has Been Damaged by Defendants' RICO Violations**

23      497. By reason of, and as a result of the conduct of the Enterprises and, in particular,  
24 their patterns of racketeering activity, Clallam County has been injured in its business and/or  
25 property in multiple ways, including but not limited to increased health care costs, increased  
26

1 human services costs, costs related to dealing with opioid-related crimes and emergencies, and  
2 other public safety costs, as fully described above.

3 498. Defendants' violations of 18 U.S.C. § 1962(c) and (d) have directly and  
4 proximately caused injuries and damages to Clallam County, its community, and the public, and  
5 the County is entitled to bring this action for three times its actual damages, as well as  
6 injunctive/equitable relief, costs, and reasonable attorney's fees pursuant to 18 U.S.C. § 1964(c).

7 **PRAYER FOR RELIEF**

8 WHEREFORE, Plaintiff Clallam County respectfully requests the Court order the  
9 following relief:

- 10 A. An Order that the conduct alleged herein violates the Washington CPA;  
11 B. An Order that Plaintiff is entitled to treble damages pursuant to the Washington  
12 CPA;  
13 C. An Order that the conduct alleged herein constitutes a public nuisance under  
14 Washington law, including under RCW 7.48 *et seq.*;  
15 D. An Order that Defendants abate the public nuisance that they caused;  
16 E. An Order that Defendants are liable for civil and statutory penalties to the fullest  
17 extent permissible under Washington law for the public nuisance they caused;  
18 F. An Order that Defendants are negligent under Washington law;  
19 G. An Order that Defendants are grossly negligent under Washington law;  
20 H. An Order that Defendants have been unjustly enriched at Plaintiff's expense  
21 under Washington law;  
22 I. An Order that Defendants' conduct constitutes violations of the Racketeer  
23 Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. §1961, *et seq.*;  
24 J. An Order that Plaintiff is entitled to recover all measure of damages permissible  
25 under the statutes identified herein and under common law;  
26 K. An Order that Defendants are enjoined from the practices described herein;

1 L. An Order that judgment be entered against Defendants in favor of Plaintiff;

2 M. An Order that Plaintiff is entitled to attorneys' fees and costs pursuant to any  
3 applicable provision of law, including but not limited to under the Washington CPA; and

4 N. An Order awarding any other and further relief deemed just and proper, including  
5 pre-judgment and post-judgment interest on the above amounts.

6 **JURY TRIAL DEMAND**

7 Plaintiff demands a trial by jury on all claims and of all issues so triable.

8 DATED this 8th day of May, 2018.  
9

10 **CLALLAM COUNTY**

**KELLER ROHRBACK L.L.P.**

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